UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x

SEKISUI AMERICA CORPORATION et al,

Plaintiffs,

v. 12 CV 3479 (SAS)

RICHARD HART, et al,

Defendants.

----------x

New York, N.Y.
January 14, 2014
10:10 a.m.

Before:

HON. SHIRA A. SCHEINDLIN,

District Judge

APPEARANCES

MORRISON & FOERSTER LLP
Attorneys for Plaintiffs
KAREN HAGBERG, ESQ.
CRAIG B. WHITNEY, ESQ.
LEDA A. MOLOFF, ESQ.
NATALIE ANNE FLEMING NOLEN, EQ.

SULLIVAN & WORCESTER LLP
Attorneys for Defendants
FRANKLIN B. VELIE, ESQ.
JONATHAN G. KORTMANSKY, ESQ.
SIOBHAN BRILEY, ESQ.

(Trial resumed)

(In open court)

MR. VELIE: Good morning, your Honor. I have a matter to take up with the Court before the witness resumes.

THE COURT: I'm sorry?

MR. VELIE: May I take up a matter with the Court pertaining to the witness before he begins?

THE COURT: Pertaining to the witness who is now on the stand?

MR. VELIE: Yes.

THE COURT: What's the problem?

MR. VELIE: The problem is this, your Honor. Yesterday you may recall Mr. Whitney and I disputed what it was that you had held pretrial regarding what is now going to be offered as Plaintiff's Exhibit 46, the AQSOL report that was prepared in May or June. Actually, you were kind enough to point out that you don't have to take our word for it; there is a transcript.

I would now like, if I may, to show you the relevant part in the transcript so you can make a ruling consistent with what you've done previously.

THE COURT: I'm not making another ruling. If I've ruled, I'll read it into the record and that's the ruling, period.

MR. VELIE: Your Honor, I'm just calling your

attention to the ruling.

THE COURT: That's fine. Whatever I ruled. Obviously your adversary knows what I said. I don't interpret my rulings. Whatever it says, it says. I don't know why I have to do this again. How could you disagree on what I said? The words speak for themselves. I'm talking to your adversary.

Mr. Whitney.

MR. WHITNEY: Yes, your Honor. I agree that the words speak for themselves. I think that there's a misunderstanding as to, I guess, the impact of them. So I--

THE COURT: The impact?

MR. WHITNEY: I would like to clarify it because we are --

THE COURT: I don't give clarifications. I'll read the words I read before. I'm sorry, I will not revisit what I've already done.

MR. WHITNEY: That's fine, your Honor.

THE COURT: Good. What page and line do you want me to read from?

MR. VELIE: Page 21, your Honor.

THE COURT: Seems like a colossal waste of time. If I've already done it, I've done it. Page 21.

MR. VELIE: Lines 6 to 9, and then again at the bottom, 24 --

THE COURT: We need context.

"MS. HAGBERG: Well, part of it, your Honor, is that one of their arguments of, defendants' argument, the company was compliant as of the time of the sale in 2009. And the fact that in 2010 there was such, the problems and of the scope that the problems were they could not have come into existence between April 2009 and May of 2010 when the same employees were running the company and the same person was in charge of CEO.

"THE COURT: If it is relevant to damages in some way because he says this is what has to be fixed now and this is the cost of fixing it and does he say the cost of fixing it just has to be done to fix the problem.

"MS. HAGBERG: He is not a damages expert.

"THE COURT: 'He' is who?

"MS. HAGBERG: He was FDA compliant.

"THE COURT: You said that relevant to damages who is going to make the link if he says you have to fix this by hiring two experts on staff who is going to then say and cost of those experts is, who is going to make the link into Mr -- makes part of that link, Ms. Kuehn makes part of that link. Mr. Morrisey makes part of that link. He just says what has to be done to fix it, then somebody still will put dollar value on it.

"MS. HAGBERG: That's correct. It's basically business records that shows what's needed. It was the recipe for that's what they had to do.

"THE COURT: Right. I can take it for a limited purpose, May and June report, to say here we are now in May and June 2010. That is what has to be done to fix the problem. Then a link that made cost of that repair, so be it. But I can't have him go back even a part, so if there are parts of the report that look back and say and this had been true for years, that part should be redacted."

MR. VELIE: That's the ruling.

MR. WHITNEY: Yes, your Honor. And we're intending only to use it to show what needed to be done. The May report, as the witness will testify, and we'll show foundation for this, is a present-time analysis of the company and that's what we're using it for. We're not-- there's no retrospective opinion in the report, which I believe the Court-- that was the Court's focus, which the Court has stated is --

THE COURT: Why are we in a dispute?

MR. WHITNEY: I'm not exactly sure, your Honor.

THE COURT: Why have we now spent eight minutes?

MR. VELIE: I'm sorry if it's taken eight minutes, your Honor.

THE COURT: It has. Why?

MR. VELIE: Because they have not redacted the report and it is our considered view that it is retrospective.

THE COURT: Well, I'll have to decide. There's nothing more I can do. Can we get started? Where is

Mr. Morrissey? Let's go. First question. I have no patience for this. I've been down the road. Now I'll have to make a decision when I hear it. There's nothing more I can do. I'm one person. It's not like there's a jury who's out of the room while we're discussing it. I'll have to go line by line.

MR. VELIE: Your Honor, I would simply --

THE COURT: Mr. Velie, I'd like to get started. Please have a seat. Please ask the witness a question. We're starting the testimony. I've had enough of the colloquy. No more colloquy. Done. Done. Finished. Time for a question.

KEVIN MORRISSEY, resumed.

DIRECT EXAMINATION (Continued)

BY MR. WHITNEY:

Q. What was your position while you were at Siemens, Mr. Morrissey?

A. I was the head of manufacturing, senior head of manufacturing.

Q. And what were your responsibilities as senior head of manufacturing?

A. I was responsible for manufacturing in our Walpole, Massachusetts facilities.

Q. And did your responsibilities include compliance with FDA regulations?

A. Yes.

Q. How long did you hold that position?

A. Years.
Q. Can you estimate how many years?
A. I had been at Siemens for many years. And I had started as a senior manufacturing manager for one product line and then I had two product lines and then I had all three of the product lines. So maybe I was all three product lines for a year, but between one and three for four or five years.
Q. We were talking about batch records earlier. What is a batch record?
A. A batch record is a group of records, or SOPs, that are used to manufacture a product.
Q. And you said that a batch record and a device history record are synonomous. Is that correct?
A. Yes.
Q. How is a batch record different from a design history file?
A. A design history file is a history of the product from the beginning until the end. So it includes your design files, your design records, and any changes to that product over its life.
Q. Would that-- would a batch record be part of a design history file?
A. A batch record would be part of the design history file, yes.
Q. When are design history files created for each product?

A. At the beginning. Design history files start when a product is developed in R & D.

Q. Do they exist for the life of the product?

A. Yes.

Q. Do they change over time?

A. They can change over time. The original records stay the same, but as you modify a product, then the validation information goes into that file.

Q. Can you describe for us in general terms the process by which a product is manufactured?

A. It's a complex product, but ultimately you would make a number of reagents, whether you mix reagents with water or DI water or whatever. You would lyophilize them in some cases, freeze dry them in some cases. And then in some cases we would put antibodies on microwells, microplates.

Q. How does a design history file fit into the manufacturing process?

A. The design history file?

Q. Yes.

A. The design history file is how a product should be made. And so the validation work that happens at the beginning of the product life reflects how that product should be made. And as changes occur over time, they need to be validated. And then the SOPs get changed based on the validation work that was done to reflect that the product performance didn't change; or, if

it did, that data existed to show that claims were justified.
Q. Can you properly make a product without a design history file?
A. No.
Q. How does a batch record fit into the manufacturing process?
A. The batch record is the only record that shows that you made a batch when you're looking back at it. So the batch record-- if you don't have a batch record, you have no evidence that you made a product the way it was supposed to be made.
Q. Was the process you just described occurring at ADI when you first arrived?
A. It was probably happening to some degree.
Q. To what degree was it not happening?
A. There were-- the design history files that I reviewed were deficient in that they didn't have-- a lot of them didn't have stability data. A lot of them didn't have the batch records that really reflected what reagents were made that made up that kit.
Q. You mentioned earlier that when you started right around your first few days, you noticed a stack of batch records on the floor of your office.

What did you do with those records?

A. I started to review them.
Q. And what did you discover?

A. I discovered that the batch records had data in them that didn't meet specification. I found that a number of raw materials had been expired. I reviewed records that weren't approved or QA released before they went into the market.

Q. And why is that a problem?

A. It's a problem because the regulations require that product is released by QA before an IVD goes into the market to ensure that they meet specifications.

Q. What should be done?

A. The records, once they're made, once a kit or set of reagents is made, they go through the process. The records are reviewed, they're ensured that they meet specification, they're approved by -- could be the manufacturing manager, and then they go on to QA for final review.

Q. Who should have been doing the QA review?

A. At the time-- well, at the time --

MR. VELIE: Objection. Your Honor, we have the same problem with this witness retrospectively testifying as Mr. Campo retrospectively opining. The records would be the best evidence of anything like this. He's about to say what he thinks happened before --

THE COURT: He can't say what he thinks happened in the past. That wasn't the question. I don't believe it called for that answer.

MR. WHITNEY: That wasn't the question, your Honor.

He's testifying as to personal knowledge.

THE COURT: Well, no. You said, Who should have been doing the quality review?

MR. WHITNEY: He's the director of manufacturing of the company --

THE COURT: Yes, but "who should have" is past tense. When should that have been? Do you want a name? Do you want a position? When are you talking about? So I'll sustain the objection. Let him stick with what he observed when he showed up.

And, by the way, he's been giving expert testimony for five minutes without objection. I have no idea why. Why you let him tell me all this that an expert would have ordinarily put in a report, I don't know. But you did and it's staying in the record.

Please continue, Mr. Whitney.

BY MR. WHITNEY:

Q. Did you tell anyone about what you found?

A. Yes.

Q. Who did you tell?

A. I told Richard Hart, I told Mark Koseki, Hugh Fryer.

Q. And what did they say in response?

A. There was nobody that was overly surprised with what I found.

MR. WHITNEY: I'd like to put up Exhibit 228, please.

THE COURT: This is Plaintiff's exhibit?

MR. WHITNEY: I'm sorry, PTX 228.

THE COURT: Let me see if I can find that.

MR. VELIE: Can we have a moment to locate it?

THE COURT: Any objection to this?

MR. VELIE: We need a moment to locate it.

MR. WHITNEY: Your Honor, all of the exhibits had been provided days ago to deal with these objections. I'm not sure what the new objection is at this point.

THE COURT: Maybe there isn't one. I just want to be sure before we start to read it.

All right. So your understanding is that if there wasn't an objection made to you in the last few days, then the parties have agreed no objection.

MR. WHITNEY: That was the parties' agreement, correct.

THE COURT: Okay. Hopefully that's right. It appears to be an April 1st, 2010 e-mail from Mr. Morrissey. No problem?

MR. VELIE: No objection.

THE COURT: Okay. Good. So this is 228. Go ahead.

BY MR. WHITNEY:

Q. Did you write this e-mail, Mr. Morrissey?

A. Yes.

Q. And did you prepare this e-mail in the ordinary course of

your work?
A. Yes.
Q. What is this e-mail? What is it saying?
A. This e-mail --
MR. VELIE: Objection. This document speaks for itself.
THE COURT: It's a summary of the meeting the same day, April 1st, 2010, that he prepared. Okay. Now I know what it is.
Q. Did you have a meeting on April 1st, 2010?
A. Yes.
Q. Was that the second day of your employment?
A. Yes.
Q. What was the meeting about?
A. This was about product 545 and that it was-- there was no record as to what buffer was used when that reagent was made.
THE COURT: Was the record of what?
THE WITNESS: There was no SOP as to what buffer was used to dilute or to make --
THE COURT: I missed the word "buffer." Okay.
Q. And if you go down to point 3.0, it says "Longer term develop and implement QC process functional and moisture."
Do you see that?
A. Yes.
Q. What does that mean?

A. That means this product didn't have a QC process to release that product.

MR. VELIE: Objection, your Honor.

THE COURT: Sustained. What this says is going forward you want them to develop and implement a quality control process.

THE WITNESS: Yes.

THE COURT: That's what it says.

MR. WHITNEY: Your Honor, can I just state for the record that he does have expertise because he's --

THE COURT: If he was going to be proffered as an expert, we needed a report.

MR. WHITNEY: I understand, your Honor.

THE COURT: Can we please continue with the next question? Thank you.

Q. And what was done as a result?

A. Well, if you go back to the top, we determined with conversations with Hugh Fryer what the correct buffer should have been to make that, and we also modified the lyophilization process to eliminate the moisture problem that they had.

Q. How did you find out about these issues?

A. I observed-- I observed them and I went into the laboratory and I talked to the technicians that worked for me and I reviewed the records as to what was happening in the

laboratory.

Q. And how did the meeting attendees react when you discussed these issues?

A. There was no adverse reaction.

MR. WHITNEY: Can we go down to the top of the e-mail, please?

Q. Who are the individuals who are listed in the "to" line of this e-mail?

A. David Teicher, Hugh Fryer, Leigh Ayres --

THE COURT: We see the names. Who are they? What were their positions?

THE WITNESS: So David Teicher was the director of tech support; Hugh Fryer was the director of research and development; Leigh Ayres was the director of quality assurance. Kate Georgelos is a manufacturing technician. She was actually the acting director of manufacturing when I was interviewing. And then Adrian Nugent was a manufacturing technician.

Q. And who are the people in the cc line? What are their roles?

A. Mark Koseki and Richard Hart, you know, I wanted them to be aware of what was going on in the manufacturing area.

THE COURT: You have to listen to the question. What were their roles?

A. Their roles in the situation were-- there was no role.

THE COURT: No, in the company. In the company.

THE WITNESS: Oh, in the company.

A. Mark was the director of CSR, corporate compliance, I believe. And Richard Hart was the CEO.

Q. Did Richard Hart respond to you when you sent him this e-mail?

A. No.

Q. Did he react in any way?

A. No.

MR. VELIE: Your Honor, I'd simply note for the record that Richard Hart's e-mails have been destroyed. Accordingly, I think we're entitled to an inference that we don't know whether or not he responded.

MR. WHITNEY: Your Honor, the witness just testified that he didn't so we're entitled to rebut that inference with actual evidence.

THE COURT: I'm sorry, the witness just testified that he--

MR. WHITNEY: That Mr. Hart did not respond --

THE COURT: I'm sorry, did or did not?

MR. WHITNEY: Did not.

THE COURT: Thank you.

MR. WHITNEY: We're entitled to rebut any inference that there was a response.

I'd like to show the witness Exhibit PTX 225, please.

We can close that document out.

Q. Do you recognize this document?

A. Yes.

Q. What is it?

A. This is-- can you go down on the e-mail? So this is an e-mail from Kate to David observing that products 170 and 175 have SOPs that state that this product has a two-year expiration date.

Q. And why was this a problem?

A. It was a problem because we were putting five years on them, four and five years on them. And that as you go up into this, David Teicher responds that he wasn't aware that there was an SOP that said that there was a two-year expiration.

Q. So he was putting four-year expiration dates on a product that should have received a two-year expiration date. Is that correct?

A. Yes.

Q. How long had Mr. Teicher been working at the company?

A. I think he was probably the second longest -- maybe the second longest employee.

Q. And what was his title?

A. I believe he was the director of a technical support, technical service.

Q. And what does that mean?

A. He worked with customers in technical issues.

Q. And, again --

MR. VELIE: Excuse me, your Honor. I hate to keep jumping up --

THE COURT: Yes, it is very disturbing. You have no objection to this exhibit, so Exhibit 225 is in evidence and it explains what it explains.

(Plaintiff's Exhibit 225 received)

MR. VELIE: I agree, your Honor. But it is plain from the questioning that what is intended to be conveyed here is that this must have been the case previously. That is simply unfair.

THE COURT: What's not unfair is what it says. "Stephanie is making new lots of product 170 and 175. She noticed on SOPs that expirations are listed at two years post-LYO for each product. The past lots made were using expiration of four years post-LYO for PN 175 and five years post-LYO for PN 170. Part of the problem is that recent batches were made not using the proper SOP."

I can't help it. That's what the e-mail says. You didn't object to it. I understand why. So of course it implies it was being done wrong in the past. That's it.

All right. Continue.

BY MR. WHITNEY:

Q. Did you at any time attempt to reduce the number of products being sold at ADI?

A. Yes.
Q. Why?
A. We had-- we were a very small organization that had over six hundred products and it was very burdensome to try to manage that many products.
Q. Why did you consider that to be a problem at the time?
A. We had a number of issues, regulatory issues, that needed to be dealt with. And what we wanted to try to do was prioritize what products were the most important to our organization and focus on those.
MR. WHITNEY: I'd like to put up Exhibit PTX 172.
Q. Did you --
MR. VELIE: Excuse me, your Honor. Just so we're plain about this, I object to this and any subsequent record -- and I'll jump up to do it -- to the extent it is used or attempted to be used to show what was happening presale.
THE COURT: I have no idea what's in PTX 172. I can't rule. So you've made your statement for the record. That's fine.
Q. Okay. Did you write the e-mail below in this exhibit, Mr. Morrissey?
A. Yes.
Q. And you wrote "We have significant deficiencies in our quality system and I have specific examples."
What did you mean by that?

MR. VELIE: Your Honor, this is exactly what we're talking about. To the extent --

THE COURT: Where is this sentence?

MR. WHITNEY: It's the bottom e-mail, the second sentence.

THE COURT: Who is this from and to? It's from Mr. Morrissey to Hugh Fryer?

MR. WHITNEY: Yes.

THE COURT: I have no problem with this. I'm totally going to allow it. You can make any statement you want for the record. You want to say anything more, Mr. Velie?

MR. VELIE: This is the problem. They're going to sum up on this and they're going to post trial briefs on this and claim --

THE COURT: And I'll deal with it. Thank you. Go ahead.

MR. WHITNEY: I'm sorry.

BY MR. WHITNEY:

Q. Mr. Morrissey, what did you mean when you wrote "We have significant deficiencies in our quality system"?

A. Well, we had the issues with batch records and using expired materials, but we also had no CAPA system, so we weren't investigating technical and customer issues.

Q. Anything else?

MR. VELIE: Excuse me. Same objection.

Q. Anything else, Mr. Morrissey?
A. There were a number of issues. There was no stability protocol, program; the design history files were lacking. There was a lot of issues regarding the quality system.
MR. VELIE: Same objection. This only goes to damages.
MR. WHITNEY: I don't understand the objection.
THE COURT: Neither do I. What does that mean, it only goes to damages?
MR. VELIE: Your Honor, you've ruled with respect to --
THE COURT: With respect to a particular report.
MR. VELIE: Okay.
THE COURT: A report. A May or June report. I didn't say, oh, this testimony is limited to damages. Mr. Morrissey came in, Mr. Morrissey was there, this is what he observed. It's part of the case.
Go ahead.
Q. Why did you consider these issues to be significant, as you stated?
MR. VELIE: Objection. He is not an expert.
THE COURT: No, he wrote "We have significant deficiencies." The question is, what does significant mean to him? I'll allow that.
A. Well, when you think about looking at the past FDA

findings, you could see that they had issues with CAPA. They had issues with a number of other systems.

MR. VELIE: Your Honor --

THE COURT: Mr. Velie, I can't try the case with your standing up at every question. I am allowing this witness to say what he observed when he took over, what he wrote in his e-mails, what the FDA reports observed. I understand it. I guess that's why the parties chose not to have a jury. I understand this.

You pointed out in your own opening, Mr. Velie, that the FDA makes observations. They do note things that are missing or expired or whatever. It doesn't mean people don't pass the audit. It means they point it out, they make their observations. Some are easily corrected; some should be corrected and are corrected.

They observe things. That's what he's saying. That the FDA noted certain things. He's repeating that. That's fine. You don't disagree with that. You put it in our own opening.

Go ahead. So you said the FDA noted.

A. They noted that we had no CAPA system; we had issues with the batch records, again, as I had said. There was a stack of probably 70 or 100 records in my office of product that was out in the field that hadn't been processed appropriately.

Q. And you continue in this e-mail to say "I would like to

have an independent auditor come in who I have identified, but Leigh doesn't want to."

Do you see that?

A. Yes.

Q. Why did you want an independent auditor to come in?

A. During the course of business in an IVD company, it's pretty common to have a third party come in and do an independent audit of what your system is really or isn't. In the case of when we talk about Intertek or you talk about the FDA, those audits are very structured. Having a third party come in and having them look at your system, they point out in total what your quality system is good in and what it lacks.

Q. And are they looking at the quality system as of the time that they're auditing the company?

A. They're looking at the-- when you have a third-party auditor come in, and we had him look at all aspects of the quality system, he's looking at it at the time and what went into how the company was performing from a regulatory perspective there.

So he looked at the design. Design is one of those issues. So he looked at design.

Q. You state that "Leigh doesn't want to," meaning Leigh doesn't want to have an independent auditor come in.

Who is Leigh?

A. Leigh Ayres was the director of quality assurance and

regulatory.

Q. So Leigh is Leigh Ayres?

A. Yes.

Q. Did she tell you why she didn't want to?

A. No.

Q. And you say, next sentence, "Mark has already agreed with me to have him come in."

Who is Mark?

A. Mark Koseki.

Q. The e-mail above, the response from Mr. Fryer to yourself, Mr. Fryer states, "It will be quite a rebuilding effort at teardown and buildup."

Do you see that?

A. Yes.

Q. Did you agree with that statement at the time?

A. Yes.

Q. Why did you agree that it would be quite a rebuilding effort?

A. It was very clear that the regulations weren't understood or disregarded for a long time there, and Hugh Fryer obviously agreed that we needed to start. And one of the biggest issues with doing what we needed to do was changing the culture to be accountable to the regulations.

MR. VELIE: Note my objection to this retrospective testimony.

THE COURT: Overruled.

Q. Did ADI ultimately retain an independent consultant?

A. Yes.

Q. Independent auditor, I believe you said?

A. Yes.

Q. When was that?

A. I think it was, like, May. May and June of 2010.

THE COURT: Wait a minute. On that last objection, this is an e-mail from Hugh Fryer dated April 16th, 2010. So I don't understand your objection at all. That is a statement --

MR. VELIE: Because he testified in conclusory form to his opinion that these things had persisted previously.

THE COURT: Well, the person said "it will be quite a rebuilding effort, a teardown and build up." That speaks for itself too.

All right. Go ahead.

Q. Who did ADI obtain as their independent auditor?

A. Advanced Quality Solutions.

Q. Are they also referred to as AQSOL?

A. AQSOL.

MR. WHITNEY: Could we put up PTX 231, please?

THE COURT: Is that the report?

MR. WHITNEY: It will explain the scope of the report.

MR. VELIE: May we have a second to pull up the

exhibit?

THE COURT: Yes, me too. 231.

MR. WHITNEY: Specifically, your Honor, I'm going to be turning to the e-mail on the SEK ending in 616 --

THE COURT: I'm sorry?

MR. WHITNEY: I'll be referring the witness to the e-mail on the last page of the document, which is the second to last page. Bates numbers will be 616.

THE COURT: I see. Okay. That is an e-mail from Mr. Morrissey to--

MR. WHITNEY: AQSOL.

THE COURT: Right. Dated April 15th, 2010.

MR. WHITNEY: Could we highlight the first two sentences, please?

Q. You wrote, "As we spoke briefly on the phone this morning, we are in need of an initial assessment audit of our quality system. Ideally, I would like to know the areas of deficiency and risk associated with that."

Do you see that?

A. Uh-huh.

Q. Was that the scope of the audit that you were hiring AQSOL to do?

A. Yes. When we talk about the scope, we're talking about the entire quality system.

THE COURT: And who identified AQSOL?

THE WITNESS: I did.

THE COURT: Had you worked with them before?

THE WITNESS: Yes.

THE COURT: Was that their entire business, to do audits, independent audits, for companies? Do you know?

THE WITNESS: It's not their entire business. They do-- that's a part of it. But they do long-term remediation as well.

THE COURT: Had you worked with them when you were at Siemens?

THE WITNESS: No.

THE COURT: No? When did you first work with them?

THE WITNESS: When I was at Orasure Technologies, the quality assurance group had an independent auditor come in to audit our quality system and it was AQSOL. So I met Jose when I was at Orasure Technologies.

THE COURT: What year was that again?

THE WITNESS: 2008.

THE COURT: Okay. Thanks.

Q. Why did you select AQSOL again to do the ADI audit?

A. I had known him from Orasure Technologies. He was thorough. He was very open and honest about his findings, and he was very willing to work with us and help develop systems. So he had the ability to make the assessment, but then to help us based on what the risk was and to get us where we needed to

go.

THE COURT: And how many audits had he done for you in your prior job?

THE WITNESS: He only did one.

THE COURT: So this was the second time you worked with him?

THE WITNESS: Yes.

Q. Did AQSOL ultimately conduct its audit of ADI?

A. Yes.

Q. Do you recall approximately when?

A. It had to have been June-ish, early June. May or June.

Q. May?

A. May or June.

Q. Did they issue a report as a result of the audit?

A. Yes.

MR. WHITNEY: Your Honor, this is where I would like to put up PTX 46.

MR. VELIE: This is the subject of our colloquy this morning, your Honor.

Q. Do you recognize what's been marked as PTX 46, Mr. Morrissey?

A. Yes.

Q. What is it?

A. It's just a report from his initial audit.

Q. Did you read it at the time?

A. Yes.
Q. Did you agree with Mr. Campo's conclusions at the time?
A. Yes. It wasn't-- it's not really a question of agreeing or not. It's these were the facts; that in his professional opinion, this is what he saw as our deficiencies.
Q. And this was the report you were just referring to from AQSOL's office. Is that correct?
A. Yes.
Q. Following this audit, what did ADI do in accordance with Mr. Campo's findings?
A. We created a quality plan in order to address the issues. We kept Jose on, or AQSOL on, to help us in that remediation.
Q. Is Jose Jose Campo, just to make the record clear?
A. Jose Campo, yes.
Q. Thank you.
Why did ADI do this?
A. Because we needed to address the deficiencies in our quality system.
MR. WHITNEY: I'd like to put up Exhibit 53, PTX 53.
THE COURT: Are we going to go back to 46? Should I keep that open?
MR. WHITNEY: You can close that down. There's a more streamlined way of going through it, your Honor.
THE COURT: One second. Let me close 46 and open 43. Okay. I've got 53 open.

Q. Do you recognize this document, Mr. Morrissey?
A. Yes.
Q. What is it?
A. It's the quality system improvement plan that we created based on the audit findings of AQSOL.
Q. And who created this document?
A. Well, I believe Yoichi was the author along with Jose Campo.
Q. And who is Yoichi?
A. Yoichi Tamenori was one of the people at ADI.
Q. And did you approve this plan?
A. Yes.
Q. Is that your signature on the page?
A. Yes.
Q. Could you turn to the page Bates numbered 1037, last four digits?
MR. WHITNEY: Can you blow up "Purpose"?
Q. Can you tell us, Mr. Morrissey, what the purpose of this plan was?
A. Well, the purpose was that this plan was going to address our lack of compliance with some of the regulations in our quality system. And so it outlined what those deficiencies were and what resources we needed to correct them.
Q. And what were the tasks that were to be accomplished as part of this plan?

A. Well, there were a number of tasks that needed to be accomplished with this. There was a plan and a task list associated with this.

MR. WHITNEY: Can I put up PTX 213, please?

Q. What is this document, Mr. Morrissey?

A. This document is the ADA quality plan for our addressing our quality system deficiencies.

Q. And who created this document?

A. I believe Yoichi Tamenori did.

Q. And did he create it at your direction?

A. Yes, and he worked closely with Jose Campo.

Q. And what are the items listed to the far left side of the document in red? What do those items represent?

A. Those items represent the items that were of the highest priority. So if you look down this, there's a number of items from a quality system element perspective that needed to be addressed.

Q. If we could just look at a few of them. The first one is identified, it says "1 CAPA (GEN039) Establish."

A. Yes.

Q. What does that mean?

A. We didn't have a CAPA system.

Q. What is a CAPA system?

A. It's corrective and preventive action.

Q. What does that mean?

A. It just means it's a system that-- or you're required to do corrective and preventive action. So if you get a customer complaint, you get a product incidence, you're required to investigate that and come to a root cause.

Q. And who requires this?

A. It's FDA.

Q. What was wrong with the CAPA system at the time?

A. It didn't exist.

Q. What was document GEN039?

A. GEN039 is a document at the highest level that just says how your CAPA system will work.

Q. Did that exist at the time?

A. Yes.

Q. So why did you say a CAPA system did not exist?

A. Because if you think about it, there were no CAPA records and there were no work instructions or SOPs to deal with how to process CAPA.

Q. And to your knowledge, Mr. Morrissey, did ADI have a functioning CAPA system prior to Sekisui's system?

MR. VELIE: Objection.

THE COURT: He wasn't there.

MR. WHITNEY: Well, I'm asking if he has personal knowledge of it.

THE COURT: He can't if he wasn't there. All I know is when he got there, he didn't find a CAPA system in place.

That's what he said. That's what he's allowed to say.

MR. WHITNEY: I understand, your Honor. There are records that we'll show that he's seen--

THE COURT: Well, we'll worry about the records at the time you put them in. Right now he can say what he saw when he got there.

He saw no CAPA system in place. Right?

THE WITNESS: Yes.

THE COURT: Right. That's it.

Q. The next item, number 2, PI (GEN012). Do you see that?

A. Yes.

THE COURT: Is PI an acronym?

THE WITNESS: Yeah, it's for a product incidence.

THE COURT: Product?

THE WITNESS: Incidence.

Q. And what is a product incidence?

A. It's just a system where if you have issues, you report them through a PI, and a PI can then be escalated to a CAPA.

Q. What was wrong with the PI system at ADI when you arrived?

A. So, there was a PI system, but what the auditors found, even Intertek, was that we didn't follow through and we didn't come to root cause or even address the PIs effectively.

Q. Mr. Morrissey, do you have personal knowledge of whether ADI had a compliant PI system prior to Sekisui's acquisition of ADI?

THE COURT: Same objection, same ruling. I'm not going to allow that. That's exactly what you asked before on Campo and I said no.

MR. WHITNEY: I thought I asked it a little differently this time.

THE COURT: No.

MR. WHITNEY: We'll move on.

Q. If you look at the top line, it says "Priority."

A. Uh-huh.

THE COURT: Wait a minute. I didn't find that. Where's that?

THE WITNESS: Third column.

THE COURT: Okay. Third column. Okay.

Q. What does that mean?

A. It just meant where it fit on the priority based on the lack of a system and the risk that that was to us.

Q. And if it had priority one, was that the highest priority?

A. Yes.

MR. WHITNEY: Can we pull back from this document a little?

Q. Could you tell us approximately how many items were on this quality plan? I think you have a hard copy version of it in front of you. It should be Exhibit PTX 213. It might be easier.

THE COURT: I'm sorry, I don't know what you want him

to count.

Q. First, I'd like to know how many priority ones are there on this list.

THE COURT: How many ones? Five.

MR. WHITNEY: That's only the first page, your Honor.

THE COURT: You have more pages?

MR. WHITNEY: Yes. That's why I was showing him the hard copy. It was easier for him to flip through.

THE COURT: I see. I see.

A. Fourteen-ish. Fourteen. And that's on the first part of it. And then there was a manufacturing site improvement that had some priority ones.

Q. And, in total, how many items, approximately, are on this list that you believe needed to be corrected when you were at ADI?

A. There were 18 from the top-level quality plan and then there were a number associated with the site. And there was another nine associated with the site, the environmental part of the site.

Q. At the time, how long did you expect this action plan to take to implement?

A. It would take two to three years to implement.

Q. And how much did you expect it to cost?

A. Probably $2 or $3 million.

Q. Why do you say this?

A. Some of the things that needed to be done could be done systematically rather quickly, but a lot of them -- validation of equipment is an expensive undertaking. Another thing is a stability program. Stability programs take a long period of time to develop and it requires reagents in your products to be able to set up a stability program.

MR. WHITNEY: I'd like to put up PTX 84, please. This is the June report, your Honor.

THE COURT: I'm sorry?

MR. WHITNEY: It's just to let the Court know, this is the AQSOL-- well, the second report.

THE COURT: Right. I just can't see the exhibit number.

MR. WHITNEY: I'm sorry. It's PTX 84.

THE COURT: All right.

MR. VELIE: And if it's necessary, same objection. And I would assume we'd get the same ruling as the previous one.

THE COURT: The only ruling you can get now is when I review these post-trial I'm aware of your objections. There's nothing more I can do now. This is the report that was prepared in June of 2010 at the company's request.

Q. Mr. Morrissey, what is this report?

A. So this looks like a follow-up report based on Jose Campo's observations.

Q. Could you turn to the second page of the document which is Bates numbered 971? Look at the section marked "Conclusions and Recommendations."

A. Uh-huh.

Q. The first paragraph, it states "ADI needs to implement the quality system improvement plan as approved. All attempts must be made to meet defined task completion dates. Completion of these tasks must be the company's highest priority."

Do you see that?

A. Yes.

Q. Did you agree with that at the time?

A. Yes.

Q. Why?

A. We were at significant risk with the state of our quality system.

Q. And the report concludes, if you turn to page 972, "ADI should also consider the need to temporarily cease production of U.S. IVD products based on continued issues associated with these products."

Do you see that, Mr. Morrissey?

A. Yes.

Q. Did you agree with that statement at the time?

A. Yes.

Q. Why?

A. Well, I think that in the situation that we were in, it

made sense for us to consider to look at our products and determine whether we should stop manufacturing them.

Q. Did ADI cease production of IVD products in the United States?

A. No, we did not.

Q. Why not?

A. Because we felt that we were putting into place guards in developing our quality system so that some of the things that happened in the past would not happen again.

Q. Earlier you had identified expired materials as one of the issues.

Was the use of expired materials one of the other problems you had uncovered when you started at ADI?

A. Yes.

Q. Do you recall having a meeting to discuss the situation with regard to expired materials?

A. Yes.

MR. WHITNEY: I'd like to put up Exhibit PTX 101.

THE COURT: Just a moment. I have to close a number of these to open any more, so just a second while I close a bunch.

What is the number you wanted now?

MR. WHITNEY: 101. PTX 101.

THE COURT: Just a minute.

Q. And do you recognize this document, Mr. Morrissey?

A. Yes.
Q. And, again, you have the hard copy in front of you.
A. No, I'm sorry. I just wanted to read it.
Q. What is it?
A. This is an e-mail that I sent based on a meeting that we had regarding expired materials.
Q. And who did you send this e-mail to?
A. Richard Hart, Mamoru Koseki, Hugh Fryer, Dicey Taylor, Bob Trinka, Leigh Ayres.
Q. And why did you send it to those individuals?
A. Those were the people that needed to understand and know about the expired material problem that we had.
Q. Can we turn to the next page? Is this the attachment to that e-mail, Mr. Morrissey?
A. Yes.
Q. And what is this document?
A. This is just a number of items that we found, critical items that we found that had been expired.
Q. And you see it lists-- is this a summary of the meeting you had? Correct?
A. Yeah. And more specifically what this shows is what we were doing to deal with the issue that we had with reagents that had expired materials in them. So we were doing stability testing to ensure that products were working the way they were supposed to.

Q. And did you draft this document?
A. Yes.
Q. There's a list of participants to the meeting. Do you see that, Mr. Morrissey?
A. Yes.
Q. Did all of those individuals attend that meeting?
A. No.
Q. Who did not attend?
A. I believe the only person that didn't attend was Richard Hart.
Q. If we could look at item 2 on the list. The column says topic and item number 2, I believe I'm pronouncing it right, is streptokinase. Is that correct?
A. Yes.
Q. What is streptokinase?
A. It's an active ingredient that is used in a number of our products.
Q. And was this expired when you had arrived at ADI?
A. Yes.
Q. Was it being used in existing products?
A. Yes.
Q. When did it expire? If you look at the description statement.
A. The streptokinase expired in June of 2008.
Q. What about the line above?

A. That expired in November of 2000 and then February of 2001.

Q. How widespread was the use of expired materials at ADI when you arrived?

A. It was pervasive.

(Continued on next page)

Q. How do you know?

A. Because we -- I did a pretty significant review of records and I asked one of the technicians that worked for me to go back and look at expired materials.

MR. VELIE: Excuse me, your Honor. The best evidence is the records themselves. They have no such records. I object to his conclusion as to what the records showed.

MR. WHITNEY: I object to Mr. Velie's statement that we have no such records.

THE COURT: Do you have the records he reviewed? Can you show him the records and say are these the records you reviewed?

MR. WHITNEY: I don't have them as exhibits, your Honor, because we reduced, as you recall, our exhibit list very substantially. We were going to do this through testimony. Now counsel says we need the exhibits they objected to in the pretrial order and we took off hundreds.

THE COURT: Are you representing that you have some of the records that he reviewed?

MR. WHITNEY: Yes. We have some of the records he reviewed.

THE COURT: All right.

Q. Mr. Morrissey, I'd like to put up 235 --

THE COURT: I have a question. There are four reagents here right in this list? That's four out of how many,

how many different reagents were utilized?

THE WITNESS: Raw materials?

THE COURT: Is it four out of 100 or four out of 500?

THE WITNESS: A hundred.

THE COURT: So the four you identified here are four out of a hundred maybe.

THE WITNESS: These are four that were in a number of products.

THE COURT: But still it's four out of a hundred, right?

THE WITNESS: This page, yes.

THE COURT: This page? I'm sorry, I don't understand your answer, "this page." What does that mean?

MR. WHITNEY: I --

THE COURT: I'm sorry, I'm talking to the witness, please.

THE WITNESS: I think there's another thing coming that has a lot more.

THE COURT: Right now this is four out of maybe a hundred different reagents.

THE WITNESS: Yes.

THE COURT: And is it all of that particular reagent that is expired, all of the streptokinase, all of the tricine?

THE WITNESS: Yes.

THE COURT: All. Okay. Go ahead.

MR. WHITNEY: Sorry, your Honor.

Q. Were there problems with other materials other than these four, Mr. Morrissey?

A. Yes.

MR. WHITNEY: I'd like to put up what's been marked as Exhibit 235.

THE COURT: Who is Edward Lazarski?

THE WITNESS: Ed Lazarski was a manufacturing technician.

Q. Did Mr. Lazarski work for you, Mr. Morrissey?

A. Yes, he did.

MR. VELIE: Your Honor, this is a summary chart. The blind data is not available. We object to it.

MR. WHITNEY: Your Honor, this is a record created in the ordinary course of business summarizing expired raw materials. The next several pages show that.

THE COURT: I'm sorry, what was his title again, this fellow Lazarski?

THE WITNESS: Manufacturing technician.

THE COURT: This is the expired raw material that you already have, I suppose, the inventory. Then we went through them all. I'll allow it.

Q. Did Mr. Lazarski create this document at your direction?

A. Yes.

Q. If we could turn to the second page. Is this the list of

expired raw materials that Mr. Lazarski put together?
A. Yes.
THE COURT: Did it have the yellow highlight?
THE WITNESS: I don't recall if it did or not.
MR. WHITNEY: I'll note for the record, your Honor, that this is not attorneys' highlighting. This is the document that existed as we received it.
THE COURT: With the yellow highlighting?
MR. WHITNEY: With the yellow highlighting.
Q. What is this document?
A. This document is just a summary of the raw materials that he found and their expiration dates.
Q. How long were some of these products expired?
A. Some of them expired in 1993.
Q. Can we blow up the column that says expiration date retesting? Did some of these products expire even prior to 1993? You have the hard copy in front of you, Mr. Morrissey.
MR. VELIE: Objection. These aren't products. These are raw materials.
THE COURT: That's true.
MR. WHITNEY: I apologize, your Honor.
Q. Did some of these reagents expire prior to 1993?
THE COURT: Yes. Some have the date in 1990. I see it.
THE WITNESS: Yes, at the top, 1990.

Q. What if anything did you instruct ADI to do with these reagents after they were discovered to be expired?
A. For the reagents or materials that we could, we discarded and bought new. If they were one of a kind, we implemented testing to insure that they would continue to work. I don't believe any of these were kept or tested.
Q. At the time you arrived at ADI was there a process in place to deal with the expiration of raw materials?
A. I don't think so, no.
Q. And what processes did you implement to deal with expired materials at the time?
A. It's hard to say we implemented a process. We just said that the standard required is not to use expired materials and we won't do that anymore.
Q. And what processes were in place at the time you arrived at ADI to insure that expired materials would not be used?
A. There was no process.
MR. VELIE: Excuse me. At the time you arrived, all right.
Q. We discussed issues with batch records earlier. Did you order that ADI undertake a review of product batch records?
A. Yes.
Q. Why?
A. Because we knew that they were deficient and we wanted to look at them and understand what the deficiencies were and

address that.

Q. What were the reviewers looking for?

A. They were looking for specifications or results that were out of spec, documents that hadn't been approved, expired materials.

Q. Did this include products that had been manufactured prior to the acquisition of ADI by Sekisui?

MR. VELIE: Objection.

A. The only records --

THE COURT: Wait, I'm sorry, one second. There is an objection. I'll allow it.

A. Can you repeat?

THE COURT: If that's what they looked at, that's fine. I understand they were products that were included prior to the acquisition, but that's not the point. That's what you looked at at the time in 2010, is that right? Okay.

MR. WHITNEY: Can the court reporter read the question back?

THE COURT: Did this include products that had been acquired prior to the acquisition of ADI by Sekisui?

A. What we did was we focused on the records that were in my office.

Q. And what did the review of those records find?

MR. VELIE: Objection.

THE COURT: I'll allow it.

MR. VELIE: Those documents speak for themselves.

THE COURT: I'm not going to look through hundreds of documents that he looked through. What did your records show?

A. That they had expired materials, they had results of data that didn't meet specification and they weren't approved.

Q. What if any steps did ADI undertake to correct batch records going forward?

A. Well, we started to create SOP's and we had an independent auditor, so a QA -- so what we did was we hired a QA manager and that QA manager reviewed all of the records before they were released.

Q. And who was that QA manager?

A. We had -- Leigh Ayres left in May. We hired Joe Azary in October of 2010.

Q. And between May and October of 2010 was there any QA manager at ADI?

A. There was no QA manager at ADI and that's one of the reasons we wanted to keep Jose around, so that we would have some QA regulatory oversight.

MR. WHITNEY: I'd like to put up Exhibit PTX 99, please?

Q. Did you write this e-mail, Mr. Morrissey?

A. Yes.

Q. And you state, "As of today all finished product batch records must be reviewed by Leigh or me." Do you see that?

A. Yes.
Q. Just to confirm, the date of this e-mail is April 22nd, is that correct?
A. Yes.
Q. Why did you write this e-mail?
A. Say that again? Why?
Q. Why, yes.
A. It's a requirement of the regulations and it was a significant change in the way we did business.
Q. Did the process of reviewing batch records exist, by the QA director exist before you wrote this e-mail?
A. No.
Q. How do you know?
A. Because the records that were, that I saw that were in my office, none of them were signed by QA, and none of them were signed by the manufacturing director either.
Q. What is an SOP, Mr. Morrissey?
A. Standard operating procedure.
Q. What is its purpose?
A. Its purpose is to have -- to have a record of how you manufacture a product and so that you can consistently make that product from batch to batch.
Q. So how do SOPs work in connection with batch records?
A. Well, the SOPs --
MR. VELIE: Excuse me, your Honor. I'm going to renew

my objection. He's not an expert. He hasn't given us a report.

MR. WHITNEY: He's a fact witness testifying about his knowledge.

THE COURT: He can explain what standard operating procedure he implemented. What is it you do when you implement a standard operating procedure? Did you do that at ADI?

THE WITNESS: Yes, we did.

THE COURT: What did you implement?

THE WITNESS: So the SOP is just really a recipe on how to make product.

THE COURT: What did you do when you got to ADI? Did you implement any SOP?

THE WITNESS: We were constantly creating SOPs but I think the question is what are the SOPs. The SOPs make up the batch record.

Q. And what does that mean, Mr. Morrissey?

MR. VELIE: Objection. The witness volunteered what had been objected to and now we're having a followup question. You asked him the correct question, your Honor, and he answered that.

THE COURT: He said the SOP makes up the batch record.

THE WITNESS: Yes.

THE COURT: I'm not sure I understand that.

THE WITNESS: So when you manufacture a product, you

might have, say, five reagents in there and you have an SOP for each reagent and when that kit goes to QA for review the batch record includes all of those SOPs as the batch record.

THE COURT: And that's what you implemented when you got there?

THE WITNESS: Yes.

THE COURT: You seem to --

THE WITNESS: It's a hard question because there were some SOPs but all of the ones that were required didn't exist so we had to fill gaps so that the batch records would be complete.

Q. What if any problems did you find with SOPs at ADI?

A. In some cases SOPs didn't exist and in some cases they just weren't clear enough as to how to manufacture a product.

Q. I'd like to turn your attention to PTX 165.

THE COURT: Wait, again, I have to close. I have too many open. Then the one we're going to go to after I have this closed is 165?

MR. WHITNEY: Yes.

THE COURT: Just a moment. Okay.

Q. Did you write this e-mail, Mr. Morrissey?

A. Yes.

Q. In the second paragraph, second sentence, states what you just testified to, that in many cases SOPs do not exist, is that correct?

A. Yes.
Q. And in the next line you state, "In many cases where SOPs do exist, they do not reflect current practices." Do you see that?
A. Yes.
Q. What did you mean by that?
A. In some cases when the technicians were making product they weren't following the SOP because they were told not to follow the SOP.
THE COURT: Wait, wait. You don't know that. They were told not to follow the SOP? That's stricken. Oh, I didn't even see you. That was -- that was stricken. That was just stricken without seeing you. That last comment is not part of the record.
Q. And approximately how many products in the company did the issues with the SOPs impact?
A. 60 percent, 70 percent.
THE COURT: Wait, wait, I don't know what that means. I'm sorry. What about those 60 to 70 percent of the products?
THE WITNESS: So the SOPs weren't current or didn't exist.
THE COURT: Weren't current or didn't exist?
THE WITNESS: Yes.
THE COURT: So if they weren't current how close to current were they? Did it vary? Some were years old, some

were days old?

THE WITNESS: Well, no. So in some cases the SOPs would be old but if you looked at the way they made it, it wasn't made the way the SOP intended it to be made.

MR. VELIE: Your Honor, again, he's guessing retrospectively here.

THE COURT: I don't think that's right. That's based on your review of what you found when you got there, right?

THE WITNESS: Mm-hmm.

THE COURT: I'll allow that.

Q. Mr. Morrissey, when you arrived at ADI did you notice any issues with the facility?

A. Yes.

Q. What were they?

A. So from a manufacturing perspective the manufacturing area was in really a type of a warehouse space and there was the shipping and receiving area was in close proximity to that so that when the shipping door was open the environment, the manufacturing space was open to the outside.

Q. And why is this a problem?

A. It's a problem because, you know, you're required to have environmental control in a manufacturing space.

Q. Were you involved in any audits while you were working at -- other than the ISO audits we discussed, were you involved in any other audits while working at ADI?

A. Yes.
Q. Was ADI audited by the FDA while you were there?
A. Yes.
Q. When was that?
A. I think it was 2011, September, October 2011.
Q. What was your role in that audit?
A. I was a primary contact with Joe Azary in that office.
THE COURT: With what?
THE WITNESS: A primary contact with Joe Azary --
THE COURT: Eazery?
THE WITNESS: Joe Azary.
THE COURT: Who is Joe Azary?
THE WITNESS: He is the director of quality.
Q. Did the FDA issue a report subsequent to its audit?
A. Yes.
Q. I'd like to call up PTX 17, please? I realize this is just the first page, Mr. Morrissey, but do you recognize this document?
A. Yes.
Q. What is it?
A. This is just the letter to Mr. Takemura regarding the inspection findings.
Q. And again, you have a hard copy there with you, but is the report contained attached to this letter beginning on the subsequent page of this exhibit? Is the report contained,

attached to the letter on the subsequent page of the exhibit, Mr. Morrissey?

A. Yes.

Q. If you look at the bottom of the -- actually, let's go back one moment. Let's look at just the date to clear the record. What is the date on the top of the letter?

A. August 29, 2011.

Q. If you look at page 6436, which is the second page of the document. The sentence starting at the bottom of the page going over to the following page, two sentences. It states, "This firm has a history of significant regulatory action. A warning letter was issued to the firm in 2004 after an inspection conducted on August 10, 2004. A followup inspection was conducted on June 21, 2005 and resulted in the issuance of a three-item FDA 483 inspectional observations described below."

Do you see that, Mr. Morrissey?

A. Yes.

Q. What is a warning letter?

A. A warning letter is, the way that it kind of works is a 483 is the first level of observations that they want you to fix. It's not voluntary, you are required to fix observations on a 483 and a warning letter is the next step that comes forth. If they're not happy when they don't feel like you're going to address the observations in the 483 they give you a warning

letter if it's a recurring item or if it's significant.

THE COURT: If you get a warnings letter you can still fix the problem?

THE WITNESS: Yes.

THE COURT: Sure. And these observations -- you've been through other FDA audits, right?

THE WITNESS: Yes.

THE COURT: Is it all that unusual to have observations noted?

THE WITNESS: You're talking about for a 483?

THE COURT: Yes.

THE WITNESS: I would say in the course of business it's not uncommon to get a 483. But I've gone through many inspections where I haven't gotten any 483's.

THE COURT: And you've been through many where there have been some observations?

THE WITNESS: Yes. We're required to expediently address those deficiencies.

Q. Have you gone through many inspections where you've received a warning letter, Mr. Morrissey?

A. No.

Q. Have you gone through any inspections where you've received a warning letter?

A. No. I don't believe I have.

THE COURT: Is this the only warning letter you

learned about, the one letter in 2004 for ADI?

THE WITNESS: Oh, for ADI, yes.

THE COURT: One warning. Okay. That's fine. Okay, go ahead.

Q. If you look at the first observation that the FDA made in 2005, it states, "procedures to ensure equipment is routinely checked were not established" -- excuse me. "Procedures to ensure equipment is routinely checked were not established, documented and implemented. Specifically chart recorders and temperature logs were not reviewed to determine if the temperatures were in specification and complete."

Do you see that?

A. Yes.

Q. Do you know if that problem had been fixed by 2011?

A. I don't recall.

Q. Can you look at the middle of the page? It says, "Observation #1 for the previous inspection, procedures to ensure equipment is routinely checked were not established documented or implemented is a repeated observation during the current inspection" --

THE COURT: I'm sorry, I don't know where you are.

MR. WHITNEY: I'm sorry, your Honor.

THE COURT: Oh, okay.

Q. "Observation #1 for the previous inspection, procedures to ensure equipment is routinely checked were not established,

documented and implemented is a repeated observation during this current inspection and listed as inspectional observation #4." Do you see that?

A. Yes.

Q. Does that refresh your recollection as to whether this was still a problem in 2011?

A. Yes.

Q. And if you look at the last sentence of that paragraph?

THE COURT: I guess the middle sentence is important, too. "Observations 2 and 3 noted during the previous inspection were observed to be corrected during this current inspection." Okay, go ahead.

Q. The sentence reads, "This current inspection resulted in the issuance of a four-item FDA 483 inspectional observation as described below." And if you look at observation number 2, it states, "Corrective and preventive action activities and/or results have not been adequately documented (corrected and verified)." Do you see that?

A. Yes.

Q. And this was an observation that the FDA had in 2011?

A. Yes.

Q. Did the FDA have the same observation in 2004?

A. Yes.

Q. And do you know if that problem was fixed at any time between 2004 and 2011?

A. Yes.

MR. VELIE: Objection.

THE COURT: Sustained. Sustained. I'm sorry.

MR. WHITNEY: I'll use the document, your Honor.

Q. When the FDA is saying corrective and preventive action activities is that a CAPA?

A. Yes.

Q. That's what corrective and preventive actions stand for?

A. Yes.

THE COURT: Wait a minute. I'm sorry, I'm not following any longer, because -- is that in the 2004 observations which are listed -- this is not a question for you, Mr. Whitney, it's for the witness. You see observations 1, 2 and 3 that we just went through for 2004?

THE WITNESS: Are they on top?

THE COURT: Before -- it's on the screen. Number one is highlighted, "procedures to ensure equipment is routinely checked." Do you see that?

THE WITNESS: Mm-hmm.

THE COURT: There were three observations made in 2004 or 2005, I can't tell. Yes, followup inspection was conducted on June 21, 2005. Do you see that? And there are three things found, right?

THE WITNESS: Yes.

THE COURT: Okay. Are any of those three CAPA?

THE WITNESS: It's gone.

THE COURT: Well, it shouldn't be gone. It's on my screen. Can we get that document back, please? Yes. There it is. Can you read that from there? Yes, you can. It says there was a three-item 483 issued after the followup inspection on June 21, 2005. If you review those three, are any of those CAPA?

THE WITNESS: No.

THE COURT: No. Thank you.

Q. If you turn to page 439.

THE COURT: 439. Okay.

MR. WHITNEY: If we blow up the top half of this document.

THE COURT: Now you're going to go through all the inspectional observations from 2004?

MR. WHITNEY: I'm just going to point out the one related to CAPA, your Honor.

THE COURT: Okay.

Q. So it states, "A warning letter was issued to the firm in August 2004 after an inspection conducted on August 10, 2004. Inspectional observation described during that inspection include," and third item states, "Lack of documentation of CAPA activities."

THE COURT: That's what the document says.

Q. Then if you look at, if you turn to page 447 --

THE COURT: 447. One moment, please. All right, 447. These are the observations from when? From now? From 2011?

MR. WHITNEY: Yes, your Honor.

THE COURT: Okay.

Q. If you look at observation number 2 at the bottom.

THE COURT: And it says, "Corrective and preventive action activities and/or results have not been adequately documented." That's what it says.

MR. WHITNEY: And the next sentence?

THE COURT: "Specifically there is no corrective and preventive action documentation available prior to July 23, 2010."

Q. Mr. Morrissey, did the FDA conclude there was no CAPA documentation available prior to July 23, 2010?

THE COURT: We just covered that. That's not a question for the witness. That's exactly what the FDA said specifically, there is no corrective and preventive action documentation available prior to July 23, 2010.

Q. And is the lack of documentation of CAPA activities the same issue that the FDA noted in 2004?

MR. VELIE: Objection. These documents --

THE COURT: They say what any say.

Q. You were present at the FDA audit in 2011, correct?

A. Yes.

Q. Was that the first time the FDA had audited the company

since 2005?
A. Yes.
Q. Was ADI audited by any other regulatory organization while you were there?
A. Yes.
Q. What organization was that?
A. Intertek.
Q. What kind of organization is Intertek?
A. They do auditing for ISO certification.
Q. What is ISO certification?
A. It's just an international standards organization and they see that you're meeting the requirements for that standard.
Q. And have you been through ISO certification audits before?
A. Yes.
Q. What is the difference between an Intertek audit and an FDA audit?
MR. VELIE: Objection. This man is not an expert.
THE COURT: I think he can testify to this. That's not an opinion, that's a fact. He's been through this. I'll allow him to testify to the difference between an Intertek audit and an FDA audit. You've been through both. What's the difference?
THE WITNESS: The biggest difference is we hire Intertek and they do an audit for our company.
THE COURT: You say you hire them. Is that a private

company?

THE WITNESS: Yes. It's a private company and companies hire them to get ISO certification.

THE COURT: Are there other companies that do that in that business? Do they have competitors?

THE WITNESS: Yes.

Q. And the Intertek audits that you've been through do the auditors go through and review every part of the audit every time?

A. No.

MR. WHITNEY: That's it. No further questions, your Honor.

MR. VELIE: Your Honor, before we undertake cross, can we take a comfort break?

THE COURT: All right. All right, let's try to return very shortly, like five minutes.

(Recess)

MR. WHITNEY: Your Honor, I just wanted to read into the record the exhibits that were admitted during direct.

THE COURT: Okay.

MR. WHITNEY: PTX 228, PTX 225, PTX 172, PTX 231, PTX 46, PTX 53, PTX 213, PTX 84, PTX 101, PTX 235, PTX 99, PTX 165 and PTX 17.

THE COURT: All right. Those exhibits are received.

MR. VELIE: May I have one moment, your Honor?

(Plaintiff's Exhibits 228, 225, 172, 231, 46, 53, 213, 84, 101, 235, 99, 165 and 17 received in evidence)

CROSS-EXAMINATION

BY MR. VELIE:

Q. Mr, Morrissey, you were kind enough to show us a record in which the FDA said specifically there's no corrective and preventive action documentation available prior to 7/23/2010. Do you recall that testimony?

A. Yes.

THE COURT: Which exhibit was that?

MR. VELIE: It's one of the plaintiff's exhibits, your Honor, but I'm going to use this to show the date order with a different exhibit. It's the 483 itself.

THE COURT: Just for my information, though, Mr. Whitney, what was the exhibit that had that sentence?

MR. WHITNEY: That was Exhibit 17, your Honor, PTX 17.

THE COURT: I still have 17 up. What page was it, do you know?

MR. WHITNEY: Yes, your Honor.

THE COURT: Could you tell me?

MR. WHITNEY: I'm just turning to it. It was page 6447.

THE COURT: Ah. Okay. Go ahead.

MR. VELIE: Your Honor, I believe you now have before you Defendant's Exhibit E and, Mr. Morrissey, do you have

Defendant's Exhibit E?

A. Yes.

Q. The first thing I'm going to read to you is from the top. It's in the first box after all the address information, your Honor. This document lists observations made by the FDA representatives during the inspection of your facility. "These are inspectional observations and do not represent a final agency determination regarding your compliance."

THE COURT: Where did you find that?

MR. VELIE: Here in this box, your Honor. It's the first box -- we'll highlight it.

THE COURT: Oh, I see it. Okay.

Q. That's your understanding of an observation, is that correct, sir?

A. What was the question?

Q. Do you understand an observation to be as the FDA states it, simply an inspectional observation and does not represent a final agency determination. You understand that?

MR. WHITNEY: Objection, your Honor. His understanding of what observation is doesn't seem relevant here.

THE COURT: It doesn't. The FDA defines it and that's that. But I'm curious if he was going to disagree with the FDA. The FDA says they are inspectional observations and do not represent a final agency determination regarding your

compliance. You agree with that, don't you?

THE WITNESS: Yes.

THE COURT: Sure. Okay.

Q. Now, let's take a look at inspectional observation number 2 on this exhibit. It's on the first page. This is what you read from. "Corrective and preventive action, activities and/or results have not been adequately documented. Specifically there is no corrective and preventive action documentation available prior to 7/23/2010." Now, you see that?

A. Yes.

Q. Now, this 483 was delivered to the company and you saw it, is that correct?

A. Yes.

Q. And this was for the purpose of you explaining to the FDA that maybe they'd gotten it wrong, isn't that correct?

THE COURT: I'm sorry, this was for the purpose --

MR. VELIE: The exhibit. The 483 form.

THE COURT: Oh, you mean the reason they give it to the company is so the company can respond if it wishes?

MR. VELIE: Yes.

THE COURT: Is that what you're asking? That's a better way to ask it. So the reason the company gets a copy from the FDA in part from the FDA is if it wishes to respond; is it true or not true?

THE WITNESS: I don't understand the question.

THE COURT: I'm going to ask it again. Try to listen to me. Is one reason the FDA gives a copy of these reviews to the company so that the company may if it wishes respond?

THE WITNESS: The company in large part is required to respond.

THE COURT: Good, okay. So that's one reason they give you a copy.

THE WITNESS: Yes.

THE COURT: Yes, okay.

Q. And did you, sir, in fact respond on July 7, 2011, to the FDA? Do you remember?

A. I believe we did.

Q. Let's take a look together at Defendant's Exhibit V.

THE COURT: Okay, we all have V now, this response is from Mr. Azary?

THE WITNESS: Yes.

Q. And you're copied on it, aren't you, Mr. Morrissey?

A. Yes.

Q. And in fact, you probably, didn't you approve this letter before it went out?

A. I probably reviewed it. I don't know if I approved it, but I'm sure we reviewed it together and determined that it was acceptable.

Q. Okay. Take a look on the second page of the exhibit.

THE COURT: Which is on the back of the first page, right?

THE WITNESS: Yes.

Q. Do you see it? Okay. Observation number 2. "Corrective and preventive action activities and/or results have not been adequately documented. Specifically, there is no corrective and preventive action documentation available prior to 7/23/2010." And your response to this is --

THE COURT: You don't read as well as I do. "American Diagnostica, Inc. ADI has had a corrective and preventive action procedure since 2006. The procedure, GENO39 (revision A) was released on March 15, 2006. The procedure referenced other procedures in the quality system for recording corrective actions such as GEN012, customer complaint procedure, GEN016, vigilance and adverse event reporting, GEN018, recall, GEN032, nonconformances, GEN023 supplier and GEN034 management review. Corrective actions were taken but were addressed in a decentralized manner using other processes within the quality system."

MR. VELIE: Your Honor, if you continue on the next page?

THE COURT: Be happy to. "There was also corrective and preventive action process used in manufacturing procedure EQPO69. We found four examples of this process being used between 2007 and 2008."

Q. Now, sir, that's what you represented to the FDA, isn't it?
A. Yes.
Q. Okay, thank you. And subsequent to your giving this letter the company received an EIR, is that correct?
A. Yes.
Q. An EIR is an establishment inspection report?
A. It's the 483.
Q. And you understand that the EIR means that the FDA is essentially satisfied and can close out its investigation and move on to other companies, isn't that correct?
A. You don't get that for two months from a --
THE COURT: No, but when you get it what does it mean?
A. When you get it you don't have to have things closed out but you can go making -- you have a plan and if they're happy with the plan that you're going to address those then they move on.
THE COURT: So they're closing out their investigation when they issue an EIR?
THE WITNESS: Not necessarily.
THE COURT: They're leaving it open?
THE WITNESS: What they're saying is once they give the --
THE COURT: Once they issue the EIR --
THE WITNESS: Once they give the EIR they've closed it out, but that could mean that you're working on the issues and

they're happy with the action you're taking.

THE COURT: So they're closing out their work.

THE WITNESS: Yes.

Q. So whatever they've observed they're satisfied that the company is dealing with it adequately?

A. Yes.

Q. I think you told us that the problem of expired materials was pervasive. Is that what you said?

A. Yes.

Q. Did you perform any recalls of any products that had been sold?

A. I don't believe so, no.

Q. And you didn't even stop selling, did you?

A. No.

Q. I'm going to turn for a minute to another topic. You were in charge of building the case against the Harts, isn't that correct, sir?

A. I was a part of it, yes.

Q. You were a COO and the person talking to the lawyers, is that correct?

A. Yes.

Q. Did Mr. Koseki report to you?

A. Yes.

Q. Did Mr. Koseki report to you in connection with, among other things, your duties in connection with this lawsuit?

A. Yes.

MR. VELIE: May I have Defendant's Exhibit five I's?

THE COURT: Five I's?

MR. VELIE: I'm sorry, your Honor, your rules require us to use the alphabet.

THE COURT: No problem.

MR. WHITNEY: Your Honor, may we have a minute to review the document?

THE COURT: Sure.

(Pause)

MR. WHITNEY: I believe this document is hearsay, your Honor. Mr. Morrissey doesn't appear anywhere on it.

THE COURT: But it's a statement of a party opponent, right?

MR. VELIE: Yes, your Honor.

THE COURT: Mr. Velie is offering it against current ADI, so to speak, the ADI of June 11, 2010 and it's a statement of that party from Ms. Taylor to Mr. Koseki. So as a statement of party opponent it comes in.

MR. WHITNEY: I'll withdraw my objection.

THE COURT: Pardon me? Oh, yes, thank you.

Q. Mr. Morrissey, you'll see that Mamoru Koseki on June 20, 2010 sent an e-mail to Dicey Taylor. The header is at the very bottom of the sheet, first sheet.

A. Yes.

Q. And the text of the e-mail is on the next page.

THE COURT: This is from Mr. Koseki and he says, "I need to find out whether Richard's old e-mail shows evidence that he knew what was going on in manufacturing. Especially communications among Richard, Vince, David and Robert are of interest. How can we trace their e-mail records? Let's discuss this next week." That's from Mr. Koseki to Ms. Taylor, right?

A. Mm-hmm.

Q. Mr. Koseki, who reported to you, told you he was doing this, is that right?

A. No. He didn't report to me at that time.

Q. So Mr. Koseki is doing this on his own?

A. I was at the company from March 31 of 2010. I didn't become the COO until October of 2010. So this predated that. I mean, Mark could do what he needed to do.

THE COURT: What was his title?

THE WITNESS: I don't remember.

THE COURT: I remember seeing -- that's okay. I saw it on one of the documents, but I can't remember the title of Mr. Koseki.

Q. In any event, you were there in June of 2010 is that correct?

A. Yes.

Q. And you were the person who was concerning himself with the

litigation against the Harts, correct?

MR. WHITNEY: Objection, your Honor. This predates any litigation. June 2010.

MR. VELIE: Correct.

MR. WHITNEY: Mr. Hart was the CEO of the company at the time.

THE COURT: Wait a minute, I'm lost. The last question was, "In any event, you were there in June of 2010 is that correct?" And he said, "Yes." Then, "and you were the person who was concerning himself with the litigation against the Harts."

When did you become involved or interested in the potential litigation against the Harts?

THE WITNESS: I don't remember.

THE COURT: Was it when he was still there?

THE WITNESS: Oh, no.

THE COURT: It was after he left?

THE WITNESS: Yes, yes.

Q. Excuse me, Mr. Morrissey, didn't you fire Mr. Hart on the very day that you filed a notice of claim against the Harts?

A. I didn't fire Mr. Hart.

Q. Did Sekisui fire Mr. Hart?

A. I have no idea what happened.

THE COURT: You don't know if he was fired?

THE WITNESS: I don't know what happened, no.

THE COURT: You don't know if he was fired. Okay. You don't know when the notice of claim was filed?

THE WITNESS: No.

THE COURT: I'm sure it's a stipulated fact. When was the notice of claim filed? The lawyers, please.

MS. BRILEY: October 14, 2010.

THE COURT: Thank you. Stipulated?

MR. WHITNEY: I'll stipulate, if that's what the document shows. I don't have it in front of me, but the document has a date on it.

MS. BRILEY: Mr. Hart was fired October 20, 2010.

Q. When did you say you became COO?

A. October. The end of October.

Q. Let's look at the top e-mail, which is from Dicey Taylor to Mr. Koseki.

MR. VELIE: Your Honor, if you wish to read it into the record?

THE COURT: Yes, I do. "Dear Koseki-san. We can go back to 2003 when the company was established here in Stamford, but Hugh has already addressed the matter. He says he has files of e-mail from Bhavna and Enri starting in 2004 when they complained in e-mails to Richard that we were making products with expired materials and they wanted his help to correct these problems. Hugh will give me these e-mails on Monday. He says most of the e-mails concern all of the products that we

have to put recently into quarantine."

Q. Do you see that?

A. Yes.

Q. Did you ever see any such files?

A. I don't recall.

Q. You don't doubt that Hugh Fryer had files as described here, do you?

A. No.

Q. In the summer -- I'm sorry -- what was your position with the company in the summer of 2011?

A. President and COO.

Q. And you were in charge of litigation or potential litigation against the Harts at that point, yes?

A. Yes.

Q. Are you aware that Dicey Taylor destroyed the electronically stored information of Richard Hart?

A. No.

Q. You didn't know that?

A. No.

Q. Do you know that she destroyed the ESI of Richard Hart in the summer of 2011?

A. No.

Q. Let's take a look together at Exhibit KKKKK.

THE COURT: Let's review what?

MR. VELIE: Five K's. KKKKK.

THE COURT: Okay.

MR. VELIE: Your Honor, the part that I would wish to call the witness's attention to -- did you want to make an objection?

MR. WHITNEY: I haven't finished reviewing the document. You handed it to me the first time just now.

MR. VELIE: I'm sorry. I apologize.

MR. WHITNEY: Your Honor, I'm not sure exactly the purpose the defendants are intending to use this document but I would argue that this is an outside individual e-mailing a company employee but not an executive or anyone with any status.

THE COURT: It's the author that counts. Who is Toni Franchina and who was Doug LeMasurier? Who are these people? Who is Toni Franchina who is Doug LeMasurier?

MR. WHITNEY: Toni Franchina is an employee at the company, ADI. I don't know her title, but she's not an executive that's for sure. Doug LeMasurier I think is their IT guy. They used an outside IT vendor.

MR. VELIE: Their agent.

MR. WHITNEY: I don't know he's their agent.

THE COURT: So he was handling the IT for the company.

MR. VELIE: Yes.

THE COURT: They outsourced their IT.

MR. WHITNEY: He would be the equivalent of an IT

individual.

THE COURT: Right. I'll allow this.

MR. VELIE: We can see from this, can we see on the last page of it, the page that ends in 32? Toni Franchina says to Doug LeMasurier, "Yeah. Do we still have Richard and Louise Harts' e-mails on our e-mail system and if we do can you tell me how to get this information quickly?"

THE COURT: That's in April of 2012.

MR. VELIE: Correct.

Q. In April of 2012 what was your function with the company?

A. Can you repeat that? I'm sorry.

THE COURT: Just what was your title in April 2012.

Q. I was the -- April of 2012?

THE COURT: Yes.

A. I wasn't there anymore.

Q. You left in April of 2012?

A. I was gone in February of 2012.

Q. The next e-mail is from Doug LeMasurier answering this. It says, "Toni, please see this response from Jamie regarding Richard Hart's mailbox."

MR. WHITNEY: Your Honor, he testified he's not even with the company at this point.

THE COURT: I don't know why you're asking this witness.

MR. VELIE: Your Honor, if you let me connect this up

you'll see it has to do with the destruction of Leigh Ayres --

THE COURT: I don't know what it has to do with the witness.

MR. VELIE: It is relevant. The witness goes on to contact Dicey, the person who does this hatchet job in the summer, and speaks to her.

THE COURT: Ask him all about that, then.

MR. VELIE: I will. But first we need to establish the date.

(Continued next page)

BY MR. VELIE:

Q. First we need to establish the date. The response is from Doug LeMasurier. He says "See this response form from Jamie regarding RHART mailbox."

Do you know who Jamie is?

A. I believe he was an IT person that worked for Doug.

MR. VELIE: May I read it, your Honor? Which would you prefer?

THE COURT: "Toni, please see this response from Jamie regarding RHART mailbox. Louise mailbox is still on the system. If you want me to set up access to it for someone please advise. I would need to give the permissions and set up in Outlook."

MR. VELIE: It's the next paragraph, your Honor.

THE COURT: Oh. The next paragraph?

MR. VELIE: Yes. This is the response that is being forwarded.

MR. WHITNEY: Your Honor, I'm going to issue a hearsay objection.

THE COURT: I'm getting lost. The one I just read is from Doug to Toni. The one below it is from Toni to Doug.

MR. WHITNEY: Correct.

MR. VELIE: This is what he's forwarding to the company. This is what the company knows.

THE COURT: No, I understand that. From Toni to Doug.

MR. WHITNEY: Your Honor, this is Doug telling Toni what Jamie -- who's another low-level IT guy -- told Doug.

MR. VELIE: Your Honor, this is plainly --

THE COURT: Anyway, I've seen it all before. I've seen it in the sanctions motion. I'm fully familiar with it. I've read these e-mails. It says "Several months ago, maybe in the summer, Dicey told me to delete Richard's mailbox."

Now, who's the "me?" "Dicey told me..."

MR. VELIE: Jamie.

THE COURT: Jamie. "I followed this by: 'Are you sure? Are you sure? Are you sure?' She was very certain that she wanted it deleted. Apparently she thought that there wasn't any more useful information or whatever they needed they captured. I would have personally archived it. She did approach me in the fall or late summer asking about what happened to Richard's mailbox.

"I reminded her that it was a directive from her. It looks like that decision came back to haunt everybody. This is not 100 percent certain, but I thought I heard that Richard's e-mail had been combed through by the Sekisui lawyers before Dicey told me to delete it. You might have to follow up with Dicey on the details."

BY MR. VELIE:

Q. Now, sir, in the preceding--

MR. WHITNEY: Your Honor, can I, just again, lodge an

objection to the matter --

THE COURT: It doesn't make any sense any longer because I quoted a lot of that in my opinion. I recall this e-mail. I can't erase it from my mind. It's a basis for a ruling.

MR. WHITNEY: I agree with that, your Honor, but counsel has repeatedly made statements and characterized it in his opening.

THE COURT: I realize that.

MR. WHITNEY: It shouldn't be taken for the truth of the matter. I understand your Honor has made a ruling, and we're not disputing that. The evidence of the fact should not be admitted for the truth of the matter.

THE COURT: I think that's right. What he's really saying is these e-mails were forwarded to Toni Franchina in April. So the company knew about this history, at least in April. And I guess he wants to ask what Mr. Morrissey knew in August. We'll find out.

MR. WHITNEY: Yes. And the company-- it can be admissible what the company knew, but not necessarily for the truth, which is I believe what Mr. Velie is intending to do.

THE COURT: It doesn't matter whether it's true. The company was told this scenario happened.

MR. WHITNEY: Yes, understood.

MR. VELIE: In addition to which, your Honor, it

reflects a statement against punitive interest, a criminal statement, by a company employee.

THE COURT: What company employee?

MR. VELIE: Dicey.

THE COURT: Yes, but we're told this by Jamie.

MR. VELIE: Understood.

THE COURT: So we don't know for a fact that Dicey said it. Jamie says Dicey says it, but that's not good enough. You know that.

BY MR. VELIE:

Q. Mr. Morrissey, in the preceding summer you were the COO. Weren't you?

A. Yes.

THE COURT: That would be August of 2011.

THE WITNESS: Yes.

Q. And you were in charge of whatever litigation activities were being contemplated against the Harts at that time. Isn't that correct?

A. Yes.

THE COURT: When did those efforts begin, roughly?

THE WITNESS: The fall of 2010.

THE COURT: Okay. Thank you.

October of 2010 is when you became chief operating officer. Right?

THE WITNESS: Yes.

THE COURT: So right away there was thought of --

THE WITNESS: Yes.

THE COURT: -- suing the Harts.

THE WITNESS: Yes.

THE COURT: Okay. He said yes.

Q. And you know, it is the fact there were no Richard Hart e-mails that were delivered to us?

A. I know that now.

Q. And--

MR. WHITNEY: And I object to that statement as being an incorrect statement of fact, your Honor.

THE COURT: Which incorrect? That there are no Richard Hart e-mails?

MR. WHITNEY: There were thousands of Richard Hart e-mails and counsel knows that.

MR. VELIE: I will modify my statement.

Q. You know that Richard Hart's ESI was deleted? You've learned that since?

A. I've learned that since. I didn't know at the time.

Q. And when you were in charge of the litigation in the summer of 2011, Dicey didn't tell you that she had ordered over the objection of the IT vendor the destruction of Richard Hart's ESI?

MR. WHITNEY: Objection, your Honor.

THE COURT: I'll let him answer that. I would think

you would want the answer.

Did she tell that you?

A. No.

THE COURT: No.

MR. WHITNEY: All right.

Q. Okay. You would have the Court believe that Dicey-- what was Dicey's rank?

A. She was in charge of everything.

THE COURT: What was her title?

THE WITNESS: I don't know what her title was. She did everything.

THE COURT: In the office.

THE WITNESS: Yes.

A. She did HR before I got there and when I was there she did customer stuff. She was Richard's sort of person that did everything. She had access to everything.

THE COURT: Anyway, she never told you that she was deleting e-mail?

THE WITNESS: No.

THE COURT: No. Okay.

Q. Did she report to you?

A. I don't remember. I don't remember. She may have reported to somebody who reported to me. I mean, ultimately they all reported to me.

Q. So when you were building the case against the Harts, did

you say, Let me see Richard Hart's e-mails?
A. No, I never looked at any of his e-mails.
Q. I see.
THE COURT: No. The question was whether you ever asked to look at the e-mails.
THE WITNESS: No.
THE COURT: No. Okay.
Q. Let's take a look at Exhibit LLLLL. The first e-mail in this chain, sir, it's on the second page, it's from Joe. Do you say Azary or Azary?
A. Azary.
Q. Azary. It's from Joe Azary. And you've told us who he is. Right?
A. Yes.
Q. It's to you.
A. Uh-huh.
THE COURT: This is in October of 2011.
THE WITNESS: Yes.
Q. Okay. And at that time you're the president and COO?
A. Around that time. I don't remember the exact date.
Q. And you are in charge at that time, sir?
THE COURT: Around that time?
THE WITNESS: I just don't remember the date I became the president.
THE COURT: I thought you became that in October?

THE WITNESS: Yes, I did.

THE COURT: 2010, I thought.

THE WITNESS: Yes.

THE COURT: You'd been doing it for a year.

THE WITNESS: I apologize. Yes.

THE COURT: That's why I pointed it out.

Q. And it was your function at that time still to concern yourself with possible litigation against the Harts?

A. Yeah.

Q. And you already sent a notice of claim. Isn't that correct?

A. I think so, yes. I mean, that's what was said earlier.

Q. You get this e-mail from Azary saying, "Kevin, could we get rid of Leigh Ayres' e-mail address?"

A. Yes.

Q. He points out "Whatever little e-mail she gets now is junk mail."

A. Uh-huh.

Q. It says "If you are in agreement, please let Dicey know so she can take care of this." Is that correct?

A. That's what it says, yes.

Q. And did you send an e-mail to Dicey?

A. No.

Q. No. You called her into your office, didn't you?

A. I don't recall that, no.

Q. You spoke with her. You did not send an e-mail.
A. I spoke with her about this, yes.
Q. Okay. And let's look at the top e-mail together, because you're copied on this. It's from Dicey Taylor to Doug LeMasurier, carbon copy to you and to Jamie. It says "Please delete Leigh Ayres from the Exchange Outlook server - totally into cyberspace. Do not archive. Kevin has approved this removal."

Did you get this e-mail, sir?

A. Yes.
Q. And when you got this e-mail, did you say to Dicey Taylor, Hey, wait a minute, you can't do that? That's a federal crime?
A. No.
Q. You didn't say that?
A. No, because --
Q. What did you say when you got this e-mail?
A. I don't recall saying anything about that e-mail because Joe had said that he had archived all of her e-mails appropriately. And that's what he said in his prior e-mail.

THE COURT: Joe Azary?

THE WITNESS: Joe Azary.

A. What he said was he just wanted to delete her e-mail address and that he had archived all of her files. And that's what I approved.

THE COURT: He said that in the previous e-mail?

THE WITNESS: Yes, this one here. It says that "We have transferred any relevant e-mails she was getting. For example, Siemens sends e-mails with regards to servicing." And this was a year after she had left.

Q. Right.

A. Over a year after she left.

THE COURT: She left in fall of 2010?

THE WITNESS: She left in May of 2010.

Q. So they transferred any relevant e-mails she was getting. "For example, Siemens sends e-mails with regards to servicing which now go to Livia and myself." Right?

A. Yes. And Joe got all of her existing e-mails, all of her archived e-mails.

Q. Where does it say that?

A. It doesn't, but that's what he said. I mean, we made sure that when she left, he got all of her e-mails.

Q. He told you that?

A. No. I mean when she left and he became QA, I gave him all of her e-mail-- all of her e-mails from the past so that he could deal with the QA/RA issues that she was dealing with, yes.

Q. And you say those are archived?

A. That's what I assumed, yes.

Q. Can you explain, sir, why it is that, in fact, Leigh Ayres'

e-mail Outlook server has, in fact, been deleted and we have not been given Leigh Ayres' relevant e-mails?

MR. WHITNEY: I'll object to that statement as being an overbroad statement. It's not a statement of fact in the record.

THE COURT: Again, you're saying they received some e-mails.

MR. WHITNEY: That's correct, your Honor.

THE COURT: All right. So what's your question given that?

BY MR. VELIE:

Q. It appears that we have no e-mails from Leigh Ayres given to us from mid-2007 to late '08. And you're saying that Mr. Azary, in fact, archived everything?

A. I wasn't there in '07 and '08. I don't know that any e-mails existed from Leigh Ayres from '07 and '08. I don't know that.

Q. So you're saying that in '07 and '08, you think it's plausible that Leigh Ayres, in fact, didn't write or receive a single e-mail?

THE COURT: He didn't say that. He said he doesn't know. He just doesn't know.

Q. When you saw this and it says "totally into cyberspace," doesn't that mean to you that it is to be gone forever, can never be traced?

A. I would say that that e-mail coming from Dicey, that wouldn't surprise me. But to me it meant that we were eliminating her e-mail address and that that was just Dicey's style.

Q. Can you explain why she says, particularly, "Kevin has approved this removal"?

A. Well, because, again, I said that--

MR. WHITNEY: Objection, calls for speculation.

A. -- the e-mail address--

THE COURT: Yes, he can't say why she said it.

But did you approve the removal?

THE WITNESS: Of the e-mail address.

THE COURT: Okay.

Q. So your version of this is that you approved only the removal of the e-mail address and you thought that that's what she had done?

A. Yes.

Q. Okay. But it's plain -- or you now know, do you not, that Leigh Ayres' ESI was destroyed and not turned over to us?

MR. WHITNEY: Objection, your Honor. What does it matter what he knows sitting on the stand now about what happened afterwards?

THE COURT: It doesn't matter much.

But do you now understand that there was some loss of some of her e-mails? Do you know that?

THE WITNESS: I guess I'm hearing it now, but my assumption and what I assumed was Joe got all of that and that her e-mail history went to Joe.

THE COURT: Okay.

Q. Can you explain then why she says "Do not archive"?

MR. WHITNEY: Objection, your Honor. Calls for speculation.

THE COURT: Right. He doesn't know why she wrote anything. That's asking him to interpret her state of mind.

Q. When you got this and it said "Do not archive," didn't this suggest to you, sir, that there would be loss of evidence?

A. Like I said, Joe Azary got everything that was-- you know, that Leigh Ayres had. That was my understanding.

Q. Okay.

A. That was my belief, that he got everything.

Q. Dicey, you said, did everything around the company, or words to that effect. Is that right?

A. She was involved in a lot of what happened at the company, yes.

Q. Does she need to use your name and authority to get things done?

A. I don't know, but maybe.

Q. Well, does she need your name and authority to get an e-mail folder deleted --

A. No.

Q. -- and sent into cyberspace?
A. No.
Q. So your version of this is she did this on her own?
A. Well, I mean, clearly I was involved in this decision. And, again, I told you what my decision was. My decision was based on e-mail address.
Q. And after you got this e-mail, you did nothing with respect to this issue?
A. No.
Q. Meaning, yes, you did nothing with respect to this issue?
A. Yes, I did nothing.
Q. I'm going to turn to another topic now. Let's look at-- do you have Plaintiff's Exhibit 17 in front of you, sir? Well, I can ask you. You were one of the people who met with the FDA. Is that right?
A. Yes.
Q. You were interviewed in connection with this, weren't you?
A. Yes.
Q. You were at the closing meeting in connection with this?
A. Yes.
Q. In your meetings with the FDA, did you tell them the truth, the whole truth, and nothing but the truth with respect to the quality assurance programs at the company?
A. Yes.
Q. And you realized after you told them the truth, the whole

truth, and nothing but the truth, they submitted an EIR, delivered an EIR showing that they were satisfied. Is that correct?

A. They were satisfied with the improvements we had made since March 2010. And he actually said that if we hadn't made those improvements, he wouldn't have passed our inspection.

Q. Where in this do you say that you are or have been in the recent past, or even in the remote past, where do you tell the FDA that you have been manufacturing products with expired raw materials?

A. We actually presented our quality improvement plan and our remediation efforts to him in our opening meeting.

Q. I asked you a different question, sir.

Did you tell him that you had been selling materials and that you did not cease selling products --

A. No.

Q. You didn't tell him that?

A. No.

Q. -- that had been manufactured with expired raw materials?

A. No.

Q. You didn't think that that was an important thing to tell the FDA?

A. No, because we had already corrected that.

Q. It was already corrected by --

A. We stopped selling products with expired material when he

got there. We had already started remediation.
Q. You didn't issue any recalls with respect to the products that you had been selling which you say you had been selling with expired product? Is that correct?
A. What was the question?
Q. Do you acknowledge, sir, that you did not do any recalls by reason of your having made product and sold it with expired raw materials?
A. No, but we did stop selling. We absolutely did stop selling products with expired raw materials.
Q. Mr. Morrissey, probably 45 minutes ago you testified that you did not cease selling products.
A. When you say I stopped selling products, we didn't stop selling them. We took the products that had expired material off and we remade them with good product. So, no, we didn't cease selling them, but we stopped selling products with expired materials.
Q. Did you in certain instances test expired raw materials and then use them in products and sell them?
A. Yes.
Q. Now, in or about May or possibly June-- do you pronounce it AQSOL? That's the easiest way to do this.
A. I say AQSOL, but you can call them whatever you want.
Q. You understand what I'm talking about?
A. Yes.

Q. In or about May or June of 2010, AQSOL delivered a report to you which you contend showed a huge number of deficiencies. Is that correct?
A. Yes.
Q. Okay. You didn't repair all of those deficiencies within two weeks, did you?
A. No.
Q. Okay. Let's take a look together at DX-Q. This is an Intertek audit, sir, is it?
A. Yes.
Q. When did they come and see you? Look on the second page, 535, "Date of audit: June 8, 2010."
A. Yes.
Q. That's approximately two weeks --
A. Yes.
Q. -- after Mr. Campo issued his report?
A. Yes.
Q. Did you attend this audit?
A. Yes.
Q. Did you tell the truth, the whole truth, and nothing but the truth to the Intertek auditor?
A. I told him what he asked us, yes.
Q. That means that you did not tell him the whole truth about what you told us here, about the deficiencies you claim you found in the company. Is that correct?

A. I wouldn't say that that's correct, but in large part when Intertek comes in, they have a designed, sort of, audit plan and they look at different things. And when they look at those things, we can choose what they look at. It's very different than an FDA audit.

Q. Now, you're using Intertek to get an ISO certification. Is that correct?

A. Yes.

Q. And you're paying them.

A. Yes.

Q. And the purpose of the ISO certification is so you can show your customers and anybody else who cares that you've been certified as being compliant. Isn't that right?

A. Yes.

Q. And are you telling me, sir, that when the ISO auditor, Intertek, came to you, you said, okay, I'm just going to answer the narrow questions you give, but I'm not going to tell you, even though I hired you, that I found a terrible mess and life-threatening conditions for patients or whatever it is that you're claiming?

A. What I will say is this, that the lead auditor from Intertek was not qualified to do these audits. He did not have IVD experience. And him and I had a very significant discussion when he was there. And, in fact, the rules have changed where he cannot do that anymore. And there was a

second auditor that was brought to that and that Intertek audit was going to be transferred to her.

So there was significant issues that I had with him in doing that, in that Intertek is the person you do want to find those deficiencies because you are paying them.

MR. VELIE: Your Honor, may I ask the reporter to please read the question to the witness? I do not believe he has addressed it at all.

THE COURT: I do have it right here on the screen: "Q. And are you telling me, sir, that when the ISO auditor, Intertek, came to you, you said, okay, I'm just going to answer the narrow questions you give, but I'm not going to tell you, even though I hired you, that I found a terrible mess and life-threatening conditions for patients or whatever it is that you're claiming?"

A. Well, first, there was no life-threatening conditions--

Q. Thank you.

A. -- but I would say that we're always trained and we give the answers to the questions that were asked.

Q. Okay. So you gave the questions to the answers you were asked and did not tell the truth, the whole truth, and nothing but the truth --

A. I told --

Q. -- to the Intertek auditor whom you hired?

A. I told him exactly what he asked us and I told him the

whole truth for every question he asked.

Q. But you did not tell him of any conditions of the kind that you would have this Court believe. Is that correct?

MR. WHITNEY: Objection, your Honor. Asked and answered.

MR. VELIE: Asked, but not answered.

THE COURT: It was answered. He said I only responded to the questions I was asked. I didn't volunteer.

Isn't that what you said?

THE WITNESS: Yes.

THE COURT: Yes.

Q. In any event, the Intertek audit report shows he had free rein, he could ask whatever he wanted?

A. Sure, he could. Yes.

Q. Okay. And he reports Azary-- I'm sorry, I withdraw that comment.

There were two auditors. And the lead auditor's recommendation, which appears on page 535 --

THE COURT: You know what he means by 535? The last digits.

THE WITNESS: Yes.

THE COURT: Okay. The recommendation says "Continued certification to ISO" -- numbers/letters -- "pending the acceptance of the corrective actions or plans for the four new nonconformities. The nonconformities identified do not

jeopardize the certification of the management system (in case of surveillance visits)."

Q. That was Savvian?

A. Yes.

Q. Okay. I want you to turn to the next page, executive summary. This was delivered to you. Is that correct?

THE COURT: You received this audit report. Right?

THE WITNESS: Yes. I was just looking at the date.

THE COURT: Well--

A. Yes.

Q. Take a look at 536.

THE COURT: I am confused. Why is the release date January 8th, 2007?

THE WITNESS: I believe that's their report date. You know, their revision control of their form.

THE COURT: Oh, I see. Thank you. Okay.

Q. Okay. You see where it says "State of the Management System. The management system was found to be effectively implemented in spite of the minor nonconformities cited"?

A. Yes.

Q. Okay.

MR. VELIE: May I have a second, your Honor?

THE COURT: By the way, the first paragraph under "General Comments" does reflect a recall of March 4th, 2010. What was that recall? Do you remember? Because it says the

recall is-- "See the attached recall notification."

THE WITNESS: I believe that happened before I got there. I think it was an incident that happened before I got there, but the recall was March 2010. So, I started March 31st.

THE COURT: Okay. So you're not sure what was recalled. Okay. Just curious.

THE WITNESS: It looks like it was reference to 822. It's right below in "Customer Performance."

Q. Okay. You look --

THE COURT: Oh, I see. Okay.

Q. You looked at Exhibits 99 and 101 when they were shown to you by Mr. Whitney.

THE COURT: Plaintiff's exhibit at this trial.

Q. Plaintiff's exhibit at this trial.

A. So what were they?

THE COURT: Exhibits 99 and 101. They were Plaintiff's exhibits that were shown on the screen. Oh, you have it in the book, right.

THE WITNESS: Yes.

Q. You see these are dated in April of 2010?

A. Yes.

Q. These were known to you, these problems, prior to June of 2010, when the ISO audit took place. Isn't that correct?

A. Yes.

Q. You didn't tell the auditor about these?

A. Well, the first exhibit, 99, we addressed on April 22nd. So that was addressed.

And then 101 is that we're just starting to put our arms around expired material and we had been developing a plan.

Q. That's in April of 2010?

A. For which one?

Q. They're both April of 2010.

A. Yes.

Q. Did you tell the auditor that there was a bunch of raw material that was expired in the plant?

A. No.

Q. You didn't think it was significant enough to tell your own hired Intertek auditor?

A. We were addressing it as an organization should.

Q. Other than the recall that you mentioned, that you didn't know much about when Judge Scheindlin asked you about it, you do not recall other recalls?

A. I believe we had some other recalls, yes.

Q. You just don't remember?

A. Well, I mean, I think we had some while I was there.

MR. VELIE: Your Honor, I need a moment to consult my notes.

THE COURT: Okay.

(Pause)

Q. You were terminated from the company. Is that correct?

A. Excuse me?

Q. You were terminated?

A. Yes.

Q. Is that a polite word for fired?

MR. WHITNEY: Objection, your Honor.

THE COURT: I'll allow it. Were you fired?

THE WITNESS: Yeah.

THE COURT: Yes or no?

THE WITNESS: Yes.

THE COURT: Yes. Okay.

Q. When you were fired, you went and worked for Jose Campo?

A. Yes.

Q. Are you aware, sir, that there were-- are you aware, sir, that there's a relevant period at issue in this lawsuit?

MR. WHITNEY: Objection, your Honor. Vague.

THE COURT: I'll allow that. Haven't you both defined the relevant period?

MR. WHITNEY: I don't believe so, your Honor.

THE COURT: Really?

MR. WHITNEY: There's a discrepancy as to what the relevant period is.

THE COURT: I didn't realize that.

MR. VELIE: It's in the SPA, your Honor.

THE COURT: So what does the SPA say the relevant period is? That's a defined term.

MR. WHITNEY: There's different provisions of the SPA. Some have date limitations and some provisions do not have date limitations.

THE COURT: Is the term "relevant period" defined?

MR. WHITNEY: No, your Honor.

MR. VELIE: Your Honor, it is the compliant-- "Material Compliance with All Laws" section talks about the period from January 1, 2006, I believe, until 4/20/2009.

MR. WHITNEY: And I believe they were quoting 4.1(4)(a), your Honor. And I agree it does state that in 4.1(4)(a).

THE COURT: Okay. So for the purposes of this question, the relevant period is January of 2006 to April of 2009.

What's your question?

BY MR. VELIE:

Q. Do you have that firmly in mind, sir?

THE COURT: I hope so.

Q. Are you aware of the company --

THE COURT: January of 2006 to April of 2009. You can remember that.

THE WITNESS: I'll try to remember.

Q. Are you aware that the company was audited 13 times

before-- slightly before, during and just after that period by either Intertek or by the FDA and, in a couple of instances, by customers? Are you aware of all of that?

MR. WHITNEY: Objection, your Honor. Misstating facts. They were not audited by the FDA between 2006 and 2009.

MR. VELIE: No, I said slightly before and slightly after.

Q. You're aware --

THE COURT: I believe there was an FDA audit in 2004, 2005 and 2011. That's all. Right?

THE WITNESS: Yes.

THE COURT: Even I figured that out.

THE WITNESS: Yes.

MR. VELIE: Correct.

THE COURT: All right.

Q. And there were two customer audits that were done during the relevant period. This is mandated by the FDA. Isn't that correct?

A. Customer audits are mandated by the FDA? No.

Q. Do you call them supplier audits?

A. We do supplier-- so you're saying did we audit suppliers?

Q. No.

THE COURT: No. Did suppliers audit you?

Q. Did anybody audit you to see if it's okay to buy your product?

A. I don't think they did while I was there.

Q. Are you aware that they did that prior to the time you were there?

MR. WHITNEY: Objection; relevance.

THE COURT: Well, if he's aware of it, he can say yes or no.

Were you aware of any supplier audits before you showed up?

THE WITNESS: No.

THE COURT: No. Okay. He wasn't aware.

MR. VELIE: This is Defendant's Exhibit S.

MR. WHITNEY: We object, your Honor. This is again dated before he was there. We were precluded from asking him any questions about what happened at the company before he was there. I don't see how defendants can open up and ask him about an audit in 2008.

THE COURT: You're probably right. What is it you want to ask about this audit?

MR. VELIE: Well, if we're clear that they're not going to make any contention in summation or post-trial briefing that anything he says relates to the prior period, if we're not going --

THE COURT: No, Mr. Velie, nobody's going to make you that promise, but there are limitations placed on what he could say about the past. He could say when he got there and looked

at the materials that had been there for years, some of them were expired. That, I've allowed him to say. Or he looked at other systems and he can say they were never in place and I can tell that from a document review. Or he can say there was a decrepid building, and it's been decrepid in some sense for years. Those kinds of things I've allowed him to say.

What do you want to ask him about an audit done, I guess by Trinity, in 2008? What would you ask?

MR. VELIE: What I would like to show, your Honor, is that this audit, which was done under FDA standards, found no audit observation --

THE COURT: What does it have to do with him? Nothing. If you want to tell me about it, if the document is admissible, tell me about it. It's got nothing to do with this witness.

MR. VELIE: I need another moment, your Honor.

THE COURT: Okay.

(Pause)

BY MR. VELIE:

Q. Mr. Morrissey, you're aware that had there been recalls, we'd be able to find them on the FDA's website?

A. Yes.

Q. Okay. Thank you.

MR. VELIE: I have no further questions for this witness.

THE COURT: Do you have any redirect?

MR. WHITNEY: Briefly, your Honor.

THE COURT: If it's brief, we can get him off the stand before I break for lunch; otherwise, you're stuck here.

THE WITNESS: I want to go home.

THE COURT: I know. I'd like that too, but I can't.

MS. BRILEY: Your Honor, may I just enter the exhibits into evidence?

THE COURT: We can do that after lunch. Let's see if we can get him done before lunch.

MR. WHITNEY: I think we can, your Honor.

REDIRECT EXAMINATION

BY MR. WHITNEY:

Q. I'd like you to look at DX-V, Mr. Morrissey.

A. What was it?

Q. Exhibit DX-V, please.

THE COURT: This one. I'll save you time. It's in the pile there, the loose exhibits.

THE WITNESS: Thank you.

Q. Specifically, Mr. Velie pointed you to statements on page 899 to 900.

A. Yes.

Q. And it states at the beginning, under Observation 2, "American Diagnostica Inc. (ADI) has had a corrective and preventive action procedure since 2006. The procedure, GEN039,

(Revision A), was released on 3/15/2006."

Do you see that?

A. Yes.

Q. And what was wrong with GEN039?

A. Well --

MR. VELIE: Objection, your Honor. He's not an expert. He's given no expert report about it --

THE COURT: No, you raised that comment. I'm going to let him tell me.

MR. VELIE: Okay.

THE COURT: Hopefully we'll get done in the next few minutes; otherwise, he's stuck for a couple of hours. Go ahead.

A. The GEN documents are very general documents that lay out how things will happen at the company. They're very generic.

THE COURT: And so he asked you what was wrong with GEN039.

A. So inherently it's not specific.

THE COURT: I see.

A. It points to a number of other documents. And the document at the time was circular and so there was no other-- there was no specific documents to deal with how to actually document and deal with a CAPA.

Q. So why did you-- why did ADI write this response to the FDA

in 2011?

A. Well, I think what we wanted them to understand was that we did have some overarching documents and that we did have significant deficiencies in the CAPA. And if you look throughout this, at what his observation was in closing this, he actually closed that observation out because we had addressed it to his satisfaction from, I think, 7/23/10.

So the CAPA system was one of the first things that we addressed. And so we wanted to give him a sense that there was an overarching document; it was inadequate. We had addressed it as soon as I had got there and he was satisfied with that.

Q. Just briefly, Mr. Morrissey, when you say you were in charge of the litigation, what did you mean?

A. I would say that I was asked to collect data and collect information.

Q. By whom?

A. By Sekisui, I think. By Sekisui employees.

Q. Were you in charge of legal strategy?

A. No.

MR. WHITNEY: No further questions, your Honor.

MR. VELIE: Just to correct one little thing.

RECROSS EXAMINATION

BY MR. VELIE:

Q. We're back on DX-- I'm sorry, PX 94. PX V -- DX-V.

THE COURT: The same document I just handed you. Yes, what's the question?

Q. You said in this letter "Corrective actions were taken but were addressed in a decentralized matter." Is that correct? The issue just wasn't a general SOP. You actually told them you had taken corrective and preventive actions.

A. What I would say is that that was Joe's observation and I wasn't involved with that level of detail. However, we didn't have CAPA documentation and the FDA auditor said that.

Q. Was Joe there during the relevant period?

A. Neither of us were there during the relevant period.

Q. You actually go on to say, when you reviewed this letter, it says "There was also a corrective and preventive action process used in manufacturing procedure EQP" whatever. "We found four examples of this process being utilized between 2007 and 2008."

Was that in the letter as well?

A. Yeah, it's in the letter.

Q. Thank you.

THE COURT: Yes? Lunch? Lunch. Okay. We are reconvening at five after two. All right.

(Recess)

(Continued on next page)

AFTERNOON SESSION

2:10 p.m.

THE COURT: Please be seated. Next witness?

MS. HAGBERG: Yes, your Honor, there was one document issue. May we address the Court on that very briefly?

THE COURT: What is it?

MR. WHITNEY: It has to do with Jeff Ellis's testimony that we intend to put in through deposition. We included what we've designated and the relevant counter designations from the defendants, but they've asked us to include additional designations. He's on their witness list and they're planning on calling him, your Honor, so we're objecting to him essentially having testified twice.

THE COURT: Is he going to be coming live on your case, Mr. Velie?

MR. VELIE: Your Honor, we were hoping to spare you a witness, so if it's played in we may not need him. It would certainly make it easier. We have to make a game day decision after they finish their case whether we need to put in a case. That's the way it is.

THE COURT: Then I'll wait. You can't put it in now because I don't want you to get two bites at that apple. If you decide not to call him you can read in the deposition portions in lieu of him going in live. Not now.

MR. WHITNEY: So we'll just conclude our testimony in

our direct on our case in chief.

THE COURT: Plus whatever counter designations. But not the additional ones, because I don't want to hear from this guy twice. If he's going to come in live, he can come in live. If he's not you can put in the deposition portions.

MS. BRILEY: Did you want me to read in the exhibits?

THE COURT: Yes.

MS. BRILEY: DX LLLLL, DX KKKKK, DX IIIII, DX V, as in Victor, DX E. That's all. Thank you.

THE COURT: I would suggest in the future I like the way Mr. Velie does it better, like five L's, four K's. It's a little easier to hear them. So let's use that convention. Five L's, four K's, whatever it is, okay?

MR. WHITNEY: Your Honor, with regard to five K's, we just note our objection that the Court was not going to accept them for the truth of the matter, but just for the fact that the conversation occurred.

MR. VELIE: Your Honor, I believe you also said that the company was on notice.

THE COURT: Yes. It was on notice, right? Okay.

(Defendant's Exhibits LLLLL, KKKKK, IIIII, V, and E received in evidence)

THE COURT: Are you going to call --

MS. HAGBERG: Yes, I am. Plaintiff calls Hugh Fryer.

THE COURT: You turned your head while you were saying

that.

MS. HAGBERG: I'm sorry. Hugh Fryer.

THE COURT: Thank you.

HUGH FRYER,

called as a witness by the Plaintiff,

having been duly sworn, testified as follows:

THE COURT: Please be seated. When you're seated state your full name for the record, spelling both names.

THE WITNESS: Hugh, H-u-g-h; Fryer, F-r-y-e-r.

DIRECT EXAMINATION

BY MS. HAGBERG:

Q. Mr. Fryer, could you please describe your professional background?

A. Yes. I was a student, I received a PhD from Yale university.

THE COURT: In what?

THE WITNESS: In neurobiology.

A. I've been working in research and development groups from that point forward with a short time being a carpenter. Would you like me to go into details about each of my jobs?

Q. No, that's fine. Just immediately prior to beginning at ADI what was your job?

A. I was a medical writer for a company in New York.

Q. Did you have any prior FDA or regulatory experience prior to joining ADI?

A. Not in the field of in vitro diagnostics.
Q. When did you join ADI?
A. October 30, 2006.
Q. And what position were you hired for?
A. I was hired as a senior research scientist.
Q. And what were your job responsibilities as a senior research scientist?
A. Initially it was to investigate new uses, new indications of use for some of our kits that we had, that we had manufactured in our facility. The next part of my duties was to develop new products.
Q. And what department were you part of, if any?
A. Research and development.
Q. How big or small was the research and development department as of 2006?
A. There were four members.
Q. And who were the other members of R and D?
A. Robert Greenfield was our director. Also we had Nick Grafos, who is a research associate; myself as a senior research scientist and Enri Guinto, who is another senior research scientist.
THE COURT: I probably missed this, but where are you employed now?
THE WITNESS: I'm employed at Sekisui Diagnostics in Lexington, Massachusetts.

THE COURT: What are you doing there?

THE WITNESS: I'm director of business development.

THE COURT: Director of business development?

THE WITNESS: Yes.

Q. Did you receive a promotion from the position of senior research scientist while you were at ADI?

A. I did. In November, October-November of 2007, the year after I started I was promoted to manager of product development.

Q. And who promoted you?

A. Richard and Louise Hart.

Q. How long did you hold the position of director of R and D?

A. Approximately one year.

Q. What was your next position?

A. Director of research and development.

Q. How long did you hold that position?

A. Until October of 2010.

Q. What happened in October 2010?

A. I was promoted to vice president of research and development.

Q. And how long did you hold that position?

A. Approximately one year.

Q. And what happened after that year?

A. I was -- my job title changed to vice president of scientific affairs.

Q. Is that the time at which you joined or ADI became part of Sekisui Diagnostics?
A. We were merged in April. I maintained the title of vice president until we merged. My title was changed to director of business development.
Q. Approximately how many employees were there at ADI when you joined in 2006?
A. Approximately 40.
Q. And what was the management structure of the company?
A. Richard and Louise Hart were the owners and below them were a number of directors and also our CFO.
Q. And who were the directors?
A. There were six groups. Technical affairs was headed by David Teicher, research and development by Robert Greenfield. Manufacturing was headed by Vince Forte. Leigh Ayres was head of the RA QA department, regulatory affairs and quality assurance group, and Charles Roy was the head of finance which also included shipping and receiving.
Q. How about Bob Trinka?
A. Bob Trinka, I'm sorry, was the director of our sales and marketing group.
Q. And how big a group was the QA RA group when you joined in 2006?
A. There was only one member, Leigh Ayres.
Q. At the time you joined the company were you aware that it

sold products that were subject to FDA regulation?

A. I did.

Q. When you joined in 2006 did you know what the FDA regulations required a company to do in order to be compliant?

MR. VELIE: Objection. This guy is an R and D guy. He's not being offered as an expert.

MS. HAGBERG: Your Honor, as Ms. Kuehn will testify, the compliance regulations apply to all aspects of the business, including R and D and what he knew for his job is relevant to, is directly relevant to our claims.

THE COURT: Well, maybe, but it depends. It's a broad question to say what do the FDA regulations require a company to do in order to be compliant. Compliant with what? They go into many areas. His area may be a specialized area. He may not know what they're required to be in compliance with, about the physical plant -- I don't know what else to suggest, but there are lots of areas, which I've already learned from reading the FDA audits. They go into lots of different areas. For him to know everything in order to be compliant with every thing I think is unlikely.

MS. HAGBERG: I'll withdraw that question and ask a more narrow one.

Q. Mr. Fryer, were you aware of what if any regulations applied to the work that you were conducting in the R and D department in 2006?

THE COURT: That I'll allow.

A. No, I was not knowledgable

Q. Did you receive any training on what regulations or reqiurements might be applicable in your job responsibilities and employment in 2006?

A. Not directly on FDA, but I was given SOPs to read.

Q. What were the SOPs that you were given to read if you recall?

A. The SOPs that pertained to research and development specifically.

Q. Was there any live training or personal instruction on compliance procedures?

A. No.

Q. And were you able to understand from the SOPs you read what was required of you as a research scientist in the R and D department?

A. No. They were very difficult to understand.

Q. Who if anyone was responsible for quality assurance at the time you joined ADI in 2006?

A. The director of quality assurance, which was Leigh Ayres.

Q. How about who was responsible for new product development and FDA filings?

A. That was the responsibility of the R and D group headed by Robert Greenfield.

Q. Do you know what a quality management system is?

A. I do.

MR. VELIE: Objection.

THE COURT: Do you know what --

Q. What a quality management system is?

THE COURT: Well, I'll take a yes or no then I'll ask him how he knows.

THE WITNESS: Yes, I do.

THE COURT: How is it you have the knowledge?

THE WITNESS: I had come to learn of it.

THE COURT: What does that mean? Can you explain how you came to learn of it?

THE WITNESS: In 2009 when I was promoted I really needed to understand the full functioning of an entire FDA organization and then began some of my own training and then was further trained later on in 2010 when we ran into some problems with the quality system.

THE COURT: Okay.

Q. Was there a quality management system in place at ADI when you joined the company in 2006?

A. There was.

Q. And what was it?

A. It was a number of different SOPs that really were designed to be able to control the company's activities.

Q. And again, were you given training on those QMS's?

A. No, not all of them. Only the narrow ones that pertained

directly to R and D.

THE COURT: Before we go into specific questions about products, your Honor, this is only if it would be helpful to you. Could you put slide 1 up please, Mr. Fisher? We couldn't bring a sample product into the courtroom because they are subject to -- you need to wear gloves and it says it has biocritical material in it, so I didn't want to try to come in downstairs but I thought it would be useful for you to have him explain what this is, since we've been talking about products and kits.

THE COURT: No harm done.

THE WITNESS: May I stand so I can actually help direct you to these?

THE COURT: Sure.

THE WITNESS: This is a typical product of our company. This is a specific class of product known as an ELISA which measures various types of proteins from blood samples, plasma samples. There are a number of different components that you could see here. If you had a laser pointer that would be helpful.

MS. HAGBERG: Your Honor, may I approach just to give him --

THE COURT: Yes, sure.

A. So this, I should add, is an IVD product both in the U.S. as well as in Europe. IVD being in vitro diagnostic

specifically used for patient testing. So there's a number of kind of general components. This is an instruction for use. This is how the kit is supposed to be used. This is simply the box in which everything is contained. This is just a foam retainer for all of these various components. This material and this material are two reagents which are actually not manufactured by our company, are purchased and then used with the kit. This is a plate which is nothing more than a piece of plastic which has molded into it very small reaction chambers, 96 to be exact. All of the reactions that take place occur in this chamber. This red little vial here is what's called the detection antibody and these two components are what are known as the standards.

THE COURT: Okay. Thank you.

Q. Is the kit what would be referred to as 822?

A. Yes. This particular kit is product 822 which is used to measure PAI-1, plasminogen activator inhibitor 1, from plasma samples.

THE COURT: Why does one want to measure that?

THE WITNESS: Low or high levels of this could indicate either a potential for clotting disorders or bleeding disorders.

Q. And the components you referred to, do each of the components have to be separately tested for compliance?

MR. VELIE: Objection. This is an R and D guy, not a

compliance guy.

THE COURT: I'll take it if he knows the answer.

A. So the answer to that is yes. In the manufacture of any product you need to test each and every component for acceptable performance and then also the entire kit needs to be tested for acceptability.

Q. Can you please describe the general procedures that you followed during the 2006-2009 period in developing product in your R and D work?

A. The general procedures were that we would have a set of requirements that were necessary for the performance of a particular product. It had all of the various, the various performance characteristics including in fact the containers and enclosures. All of those were predefined and then we would then develop the product based on our knowledge of the scientific field and then using whatever materials that would be appropriate.

We would then create the product, create pilot product, do some testing and that would then be transferred to manufacturing where it would be manufactured into a product. In the course of that testing would be performed and then usually some of the testing also included clinical trials.

Q. And what kind of forms did you create or maintain as part of your working on the development of the new product?

A. We really didn't use many forms. Most of our work was

captured in laboratory notebooks.
Q. Do you know what a DHF is?
A. I do know what a DHF is.
Q. As part of your work did you create portions of the file that would be part of a DHF?
A. Since we really weren't trained very well on what would be components of a DHF we really did not. We only captured our notes in laboratory notebooks.
Q. Do you know what a product stability program is?
A. I was.
Q. Is that part of the things you had to consider in developing a property and researching how it might work?
A. That's what we were supposed to know. Unfortunately it was something I was not trained in.
THE COURT: What is a DHF?
THE WITNESS: DHF is a design history file.
MS. HAGBERG: Trying not to repeat, your Honor. I was trying not to use the full name.
THE COURT: Now you can.
Q. How did you keep track of expiration dates for the components that you were working with?
A. Although there was some testing that was done on some of the components many of the components that we, that we manufactured were, we made what we considered to be educated guesses on what the expirations were. We would then, during

manufacturing process or QC processes sometimes do some testing to assure that the stability was what was claimed. It wasn't as rigorous as what we now know.

MR. VELIE: Your Honor, can we be clear that this is in the R and D that he knows something about that he's not claiming he knows something about manufacturing?

THE COURT: I can't hear you, Mr. Velie.

MR. VELIE: I'm sorry, let me see if I can reach this. May we be clear that he is still speaking about R and D and not manufacturing about which he is not expert?

THE COURT: He was clearly talking about manufacturing in that last answer, there's no question.

MR. VELIE: Right, and I believe that goes beyond --

THE COURT: Maybe we should find out the basis for his knowledge. You said, "Although there was some testing that was done on some of the components many of the components that we manufacture or we made were what we considered to be educated guesses on what the expiration dates were. We would then during manufacturing or QC processes sometimes do some testing to be sure that the stability was what was claimed."

How do you have the knowledge of what was going on in the manufacturing side?

THE WITNESS: The function of stability testing really resides in the R and D groups. That was not the practice in our company at the time. There was some stability testing that

was done by the R and D group. However, again, that is normally what happens. In our company a number of groups would participate.

THE COURT: If you can't tell me the basis of your last answer I'm going to strike it. It was all about what was happening in the manufacturing process. Did you have firsthand knowledge of that?

THE WITNESS: Yes, I did.

THE COURT: In what capacity did you have firsthand knowledge of the manufacturing process?

THE WITNESS: Because in addition to my role as an R and D scientist I also manufactured kits.

THE COURT: Personally?

THE WITNESS: Personally.

THE COURT: Okay, then I'll allow the answer to stand.

Q. Was R and D in the time period of 2006 to 2009 also manufacturing products that they were developing?

A. Several of us were, yes.

Q. Do you know what a batch record is?

A. I do.

THE COURT: I'm sorry, a what?

MS. HAGBERG: A batch record.

THE COURT: Batch --

MS. HAGBERG: Batch record. Would you like me to ask him what it is, your Honor?

THE COURT: Sure.

Q. What is a batch record?

A. A batch record is a compilation of records that are associated with the manufacture of a particular product. As I pointed out earlier, there's a number of components that go along with each and every kit that we manufacture, in that we have production type of standard operating procedures or work instructions. We also have testing work instructions, or SOPs. In addition to that, many of the components also, we have information about the components in the form of what's called certificates of analysis which are usually issued by manufacturers of these raw materials. In addition, any other, anything where a record that is required to really truly understand how a particular product is being manufactured has to be put together as a file. In our company we used to do those as records, as hard copy files. But everything that's known about the manufacture of a product needs to be in that file for reasons of traceability according to the FDA.

MR. VELIE: Your Honor, this is expert testimony on manufacturing. He is not an expert on manufacturing.

MS. HAGBERG: Your Honor, it's based on his personal experience --

THE COURT: I think it is.

MS. HAGBERG: -- in 2006 to 2009 in the company.

THE COURT: I think it is. Also counsel didn't really

offer. She asked if I wanted it defined again.

MR. VELIE: Then he went on and gave a non-responsive answer. He then gave his opinion about what was going on in the company, not what a DHF is.

MS. HAGBERG: Your Honor, may I ask another question that maybe will establish a foundation?

MR. VELIE: No.

MS. HAGBERG: Thank you, Mr. Velie.

MR. VELIE: You're welcome.

THE COURT: I'll just allow the answer to stand and move on. Frankly it's all background anyway. Go ahead.

Q. Did you create or work with batch records in R and D during 2006 to 2009?

A. I did. Again, as I mentioned before, I was involved in manufacture of specific products and so, yes, I created batch records.

Q. Can you look at what is Plaintiff's Exhibit 210 in the binder in front of you? And it also will be on your screen there.

THE COURT: Which one is it?

MS. HAGBERG: Plaintiff's Exhibit 210. PTX 210.

MR. VELIE: May we have a moment?

THE COURT: By the way, that kit you showed me a picture of on Exhibit 1, I think it is, what does that sell for?

THE WITNESS: I believe the cost is about $350.

THE COURT: To whom does that kind of a kit get sold? It's not to consumers like me, right?

THE WITNESS: No.

THE COURT: Who gets it?

THE WITNESS: So IVD's, the running of an IVD product is only in clinical laboratories so this particular kit was sold to a number of different companies including Quest diagnostics.

THE COURT: Thank you.

Q. Could you please look at PTX 2010?

MR. VELIE: It's 210. Excuse me, what is the foundation, your Honor? His name doesn't appear on this.

THE COURT: You have seen many of these documents?

THE WITNESS: Many.

THE COURT: In what capacities have you seen them?

THE WITNESS: In work remediating some of the difficulties we had with some of the kits and also investigations into some recalls.

THE COURT: I'll allow him to explain what this document is.

Q. What is PTX 210?

A. This is actually a folder cover for the batch record for product 822 and this particular lot number as you can see is 072401. The lot number 072401 refers to the batch that was

made in 2007. This is product 24 and this is the first of the batches made in that year.

THE COURT: I'm sorry, I don't follow all of that. So product number 822, is that a single kit?

THE WITNESS: Yes, it is.

THE COURT: One kit?

THE WITNESS: Yes, it is.

Q. And what is a lot number or what is a lot? What do you mean by lot?

A. A lot is all the components that are manufactured and all of the various information that is collected for the manufacturing and testing of a particular kit and usually there's more than one, so we call that one lot. So there could be anywhere from one to a hundred.

Q. And is there a date on which this lot was released, this product was released?

A. You would have to --

Q. You can turn to some place in the -- maybe direct your attention to the next page.

A. The next page, actually, if I may stand, your Honor, and use my laser pointer?

THE COURT: Sure.

A. So this particular lot --

MS. HAGBERG: Your Honor, would it be okay if he stepped down? We're worried about him leaning down with the

computer. Is that okay?

THE COURT: He's fine.

MS. HAGBERG: You're okay right there?

THE COURT: He's fine where he is. He can do it with a laser pointer.

A. So the box has a label on it here which has the expiration date of -- so let me explain to you what this form is. This form is the label request form for all the labels that are used for the kit itself. This is a very important form because it gives all of the information that is necessary for any laboratorian to be able to understand what each individual component is as well as the kit. There's a number of different columns here and the first column is the lot number. Now, the lot number for some products are written as, in this case, for example, is 070123. What that refers to is actually the date on which that product was manufactured. It's listed as year year, month month, day day. So in this case this particular component was made on 2007, January 23rd and this refers to that 96-well plate that I referred to earlier.

This component is another example, is the 0 nanogram per mil standard, that's one of the white vials that was shown. That particular one was manufactured on 2007, January 22nd, etc.

Now, there are two components which I had explained previously that we did not manufacture but we purchased through

another company, and these have a different lot number and that lot number is assigned by the manufacturer of that particular component.

One thing that I can point out is that each of these also has an expiration date. For this particular kit each of the components that were manufactured by ADI has a one-year expiration. So the expiration dating is slightly different from what you see for the lot number. The expiration dates here are written as year year year, month month, day day, so this particular component which was manufactured on 2007 January 23rd expires on 2008 January 23. The same is true with the other three components.

Q. So the components may have different expiration dates, the group of components within a particular product might have different expiration dates, is that correct?

A. That's correct.

THE COURT: They might, but in fact they're all assigned one year.

A. In this particular kit all of these were assigned one year.

Q. But they have different month and date?

A. Correct.

THE COURT: No, never. The same month and date one year later. In other words, each one is exactly one year from the lot.

MS. HAGBERG: I understand what you're saying, your

Honor.

Q. And what is the --

THE COURT: What I don't understand is the quantity requested. Is that 300 plates or are you going to make 300 kits?

THE WITNESS: Correct.

THE COURT: So even though it says product number 822 you said that was a single kit, but you're going to make 300 kits with 300 plates.

THE WITNESS: Correct. Depending upon the kit that's being manufactured you might have multiple components of the same type in one kit. So, for example, you might have two of these --

THE COURT: Two plates in one kit?

THE WITNESS: Two plates in one kit would be an example.

THE COURT: Why would you do that?

THE WITNESS: Depending upon the need for the kit.

Q. What are the different signatures that appear at the bottom of this document?

A. So there is somebody that usually requests the kit and that usually comes from somebody at the time -- it was usually the technical affairs group. The signature here was the, I guess the person, this was somebody who, from manufacturing who looked at the labels and did the label test. And then of

course there's always dates. And so one of the things I should point out is that on all of the forms that we have which is part of a batch record, and this is one of the forms that's included in a batch record, every item should have some information associated with it.

Anything that doesn't have -- if it's a blank space should have a crossout with an initial as well as a date and you can see that this form is fairly complete with the signatures of everybody and the dates for which they performed whatever duty that they had --

THE COURT: Actually, one person's signature occurs four times. Who is that?

THE WITNESS: Yes. This is a manufacturing associate that was involved in testing the label, inspecting the label.

THE COURT: You actually know that person?

THE WITNESS: I do.

THE COURT: What is his name?

THE WITNESS: His name is Gus Sempertegui.

Q. Could you turn to page 1877, please?

THE COURT: Same document?

MS. HAGBERG: Same document.

THE COURT: That's the letter from David Teicher?

MS. HAGBERG: Yes.

Q. What does this page show?

A. What this page shows that there is, there's information

that we provided to Quest Diagnostics claiming that this particular kit was tested, so tested on what's called quality control retentions. In other words, when we manufacture a kit, we also keep some behind for further testing. From Imubind Plasma PAI-1, which is the 822 kit and the particular lot that this is associated with, it gives you a little bit of an idea of what was tested and that was the release criteria that's the final quality control that was performed on this kit, and it passed this QC and therefore they extended the expiration date by three months. The date of the letter is February 7, 2008. The expiration, the new expiration date is April 22, 2008.

Q. And could you please turn to SEK 883 in your binder? It will be up on the screen, too.

THE COURT: Is that a different exhibit?

MS. HAGBERG: No, no. Sorry, your Honor, we're just walking through a batch record so you can see the different parts of it.

THE COURT: Look for 883.

A. This is what's known as the work order form. This is issued at the very beginning and this tells the manufacturing associates and the manufacturing department how many kits are requested and who the requester is and the date of that request. When the completion of the manufacturing occurs and the quantity that's actually produced, you can see there's a discrepancy here and that's because they accounted for two

extra kits that were to be in QC retaining. The number that was released, which was the 300 that was requested and the two that was retained, and very importantly is the release date and the release date was 2/6/2007 and that was released by VF and that was Vince Forte, our director of manufacturing.

Q. Do you see anything on that document otherwise that is not consistent with what it should be?

A. No, this looks in order. Except -- yes, this looks in order.

Q. Could you turn to the next page, SEK 884?

A. Yes.

Q. What is this page, SEK 884 of PTX 210?

A. Okay. There's, this is a particular form that was a generalized form for running certain types of, manufacturing certain types of materials. This is an unusual form for this kit because this is not an SOP that's associated with the manufacture of this kit. So this is outside the normal practice of the manufacture of this particular product. It does allow for some information to be gleaned and that is that the material that was being tested was the 822 detection antibody -- that was the little red vial -- and the date it was performed on; what was the lot number of this particular material was 070123 which was the material that was included in the kit. And then the product or part name and then what product it was used in.

There's two crossouts here. There's no expiration date and no RC. There's a line that is drawn through each of these and it's not clear who and when those lines were drawn through. But very critically, there's no expiration date assigned.

It has some type of procedures which are a little bit difficult to really truly understand and are far less than the procedures normally used for the manufacture of this particular material. And then it also has some information below which is that -- beyond these pieces of information, this down here which is very important is that it makes commentary that it was concentrated before centrifugation.

Now, the problem with that is that is a process which is not what's called validated, validated meaning it hasn't been tested to be sure it's okay to do and it also doesn't take into consideration any problems that could occur later after the kit was released into the marketplace. So these are some of the unusual findings that are here.

The other thing that's also --

THE COURT: These comments were made in 2007, right?

THE WITNESS: Correct. Correct.

A. Now, the other problem is that almost all of our components and everything that we manufacture should be reviewed by usually somebody else and there is actually no review whatsoever on this document. So it's not clear that anybody

reviewed this document.

MR. VELIE: Your Honor, note my continuing objection to expert testimony which we were never put on notice of.

THE COURT: It's not expert testimony. Objection overruled. Obviously noted on the record.

Q. Mr. Fryer, could I, just before we leave this, could I direct your attention to the line that is numbered 5 with a circle around it, still on SEK 884? What's that line showing?

A. I'm not sure which one. Oh, this one here?

Q. Yes.

A. It says they aliquoted 150 vials with 150 microliters and I can't read that word.

Q. Why is there a crossout there? What does it mean to you?

A. I think in this particular case it was not very readable so they crossed it out to make it a little more clear. Somebody put their initials there. However, there was no date. Same thing is true here. I'm not really sure what this means and there's initials here, for instance, that I can't quite fathom.

Q. Could you turn to page SEK 887, still in PTX 210?

A. Yes..

Q. Your Honor, I'm skipping a couple of pages but if you want him to go through -- okay.

THE COURT: My only question is, is this a sample just to walk through?

MS. HAGBERG: This is a sample so you see what it is.

THE COURT: Nothing particular about this one?

MS. HAGBERG: Just what the issues are with it.

Q. Now can you turn to SEK 887? What does this page show?

A. So the SOP that was used in this case is ELIS012 and this is the form which is the first form of this particular SOP. The forms are what are to be filled out and then included in the batch record as hard copy.

This is actually for the preparation of the zero nanogram per mil PAI-1 standard. That's one of the white vials and this is what's being used now. There are some unusual things going on here that's not quite easy to understand. First of all, there looks to be several different lots of this depleted plasma that were combined. It's not stated explicitly in the SOP that it can be. And, number two, it's a little confusing, I'm not sure if for, example, 0701015 was actually used at 50 mils or there was some other volume associated and that was left off. And the line itself has no initial or date after it.

The other problem, again, is that we continued to talk about expiration dates and this batch record, there is no expiration date that was filled in. So this is a piece of information that again was very critical to the manufacture of this kit and required but, yeah, it was not filled in.

The other interesting part about this particular record is, as I pointed out earlier, this particular lot was

released in January of 2007. This particular record was not reviewed until 6/25/2007, fully four to five months after the release of the kit.

THE COURT: Where do you get that?

THE WITNESS: Right at the very bottom the review date. I'm not sure whose initials these are, but the review date is very clear down here. So batch records should be reviewed before they're released and again all information should have been filled in but this clearly couldn't have been filled in because the date is much later than the release.

THE COURT: But here's a expiration date. So before there was a blank just above in I, but II has an expiration date.

THE WITNESS: Correct, but this is a little bit different. What this is asking for is not the expiration date of this particular material. It's asking for the expiration date of this particular material.

THE COURT: Well, of the final product.

THE WITNESS: This is not of the final product, no.

THE COURT: Where it says step 9.6-9.10 record final product data?

THE WITNESS: Correct. This is the final product data for the components of the kit. This is actually and I'm sorry I didn't make this clear, this is actually the information about the raw material. So in addition to the components

having expiration dates one of the things that is a requirement is, according to this form anyway, seen by the FDA is all of the raw materials by themselves should have information for the sake of traceability including especially the expiration date of the raw material.

Q. What's PAI-1 depleted plasma?

A. It's critical raw material in this particular case which forms what's called the basis of the matrix for which the standard is then diluted in.

Q. And could you turn to page SEK 88 -- I'm sorry -- SEK 7890.

A. Okay.

Q. And what is being shown on page SEK 890 of Exhibit 210?

A. If you enlarge this, I can tell you. This is ELIS015, again form 1, which is the preparation for the depleted plasma which we saw in the previous -- the previous form and this is the appropriate SOP for this particular product. This particular column is a column which is used for the manufacture of one of the basic materials in the kit itself, and you could see a lot of information has been left off.

This column is called the 395G column. The vendor is not listed here. And I know that the vendor actually is -- we had manufactured that particular component. That particular column. The lot number for this is 2005 June 29. 2005 is two years, a year and a half before that, before the use of this column. So there's information that's missing here is, number

one, vendor receiving code and expiration date with no date or initial as to who did the crossout. Number two is that I know in the manufacture of this particular component, I know because I worked on this kit, that the expiration of this particular column was never investigated and so we don't know, for example, if this material was still functioning as it should.

Q. And could you please turn to -- were you finished with everything you had to say on that page?

A. I am.

Q. Could you please turn to the next page, 891 in Exhibit PTX 210?

A. If you could highlight this, this is the same, okay, this is a different component. It's actually not a component. This is a material that's used in that column that was shown previously. We have glycine that's here, and again this is the information required for understanding where this glycine came from, and the vendor is Amerisco. We have a lot of other information but we're lacking an expiration date. There's a crossout.

Q. Please turn to the next page, SEK 892. What is this page showing?

A. This is from another material that's used with that same column that I was referring to earlier. This is the SOP that is used for the manufacture of that particular material and once again what we're seeing here is two things. Number one is

there's no expiration date. Number two, we have a crossout here in that two of these were used. Again, no initial, no date, and this is not part of the SOP. The SOP states explicitly that one packet is to be used. This was actually used for the manufacture of double that volume.

Q. Can you tell from the pages that we just looked at what the date of the testing was compared to the date the letter was sent to Quest?

A. So if you're referring to in fact the letter which was enclosed there is some testing information that is provided in the pages right after that letter. They were included, so if you can show those, I'm not sure --

Q. If you could look at your hard copy and direct us to the page.

A. So, yes, it's page SEK 91879. So this was the protocol that was supposedly used.

THE COURT: Wait. I'm sorry. You want us to go to 879 or not?

THE WITNESS: 879, correct. I'm sorry.

A. So there's a number of pieces of information here. However, what is completely lacking is really what was actually done in this particular validation. And so -- I'm sorry if I use that term. Validation means nothing more than testing to a particular acceptance criteria, acceptable performance. So the title of this document is extension of expiration date of kit

lot 072401 which is the lot kit we're talking about. The product is 822 with new standards and DAB, I'm not sure what that means. The expiration date of this kit is 2008 January 22.

These are all of the various components that we saw actually in the batch records so that the initial form I showed you with a label, the label request form had all of the same information in it. So these are the materials that were tested. In addition to that, there are these two materials here which are not clearly defined, but I know from my experience that this is actually an independent control which is issued by another manufacturer and that manufacturer, they manufacture this material specifically for testing with our, with kits like ours for PAI-1 kits.

This is the lot number of the kit that would be the material that was used. There's no expiration date, but as you can see here, there was a value, which is probably taken from the certificate analysis, the C of A, which says 52.9 plus or minus 6.3 nanograms per mil. In other words, this particular material when you measure it should have a value of anywhere between 46.6 to 59.2 nanograms per mililiter. Likewise, another lot of this same material should have a value in the range of 56.3 to 71.7 nanograms per mil.

One problem with this form, there are many, and that is we don't know what was actually done. We don't know in fact

who performed the assay. It was not approved prior to the actual testing, and there's obviously as we go on, there's no report about what this testing actually means. That is not -- that is not an appropriate way of actually performing this.

Secondly, this tests to the date that this was being tested on. This does not test the date at which we extend the expiry to, so this was tested I believe on, if you scroll down, please, down to the -- I'm sorry, it would be the next page. It would be 91880. If you could highlight this section here. The plate was tested on February 2nd -- February 8, rather, 2008 and the time was 2:31 p.m. That's the testing date. This is a date stamp that's issued by the software used for this particular plate process. And you can see this is, as I was describing before, this is a 96, this is the representation of the 96-well plate with some values associated here. That's the readout.

From here again we can't really see clearly what are on all of these wells except for these two sets of wells which is 277 with the lot number here and another one here. These are presumably, these are in fact the controls that were being tested against the ones that I pointed out earlier that's made by another manufacturer.

If you scroll down a little bit farther, I'm sorry, let's go to the next page, please. 91881. This is actually the data that was collected and this is the standard curve.

The standard curve has assigned values based on the use of the kit itself and the readout from that are here.

THE COURT: I'm sorry, where's the readout?

THE WITNESS: These values that are here, the individual wells, and then this is the mean value so typically we run these in multiplicities and the mean for that and standard deviation is right here. The standard deviation divided by the mean gives you what's called a CV and that's what's listed here.

Q. When you say here, you're referring to that column --

A. This column here. I'm sorry.

Q. Page 88 --

A. The very last column where it says CV. All of the coefficients of variation are here. If you scroll down a little further on this page, please. The mean result for the samples which we saw in the page before this were the controls themselves. There are two values; one for the first control and one for the second control. This one reads 42.986 and this one reads 46.204. If you control --

Q. If you could go back to SEK 879. I think that's the page you're referring to.

A. If you highlight this again you can see that neither value is actually contained within this acceptance criteria. It had to fall within here. Neither of those values actually fell within that range.

Q. And what does that tell you?
A. That tells you that the kit failed. Now, the other problem with this testing is that if you scroll up to the top of the page, the date was February 8, 2008. The letter that was dated to Quest was February 7, 2008. That means the testing that was done actually was issued, was performed after the issuance of the letter. So as far as we know, because the batch record is the only complete document that we have and all of the materials in that are supposed to represent what was manufactured, there is no other document in there to indicate that any testing was done before the 2007, so we can only conclude from this batch record that the testing was done after we give notification to Quest Diagnostics.
Q. And could you turn, please, to SEK 1895, still on Exhibit 210?
A. Yes.
Q. What is this page?
A. If you can highlight this portion up here? The top of the page. This is, again, another generalized SOP. This is not a specific SOP for the manufacture of this particular product.
Q. So you're saying that's the wrong SOP to be using for this?
A. That is correct. And as you can see just from the very top of this page, there were a number of different crossouts. It's very confusing as to what was done. This is very somewhat of a problem for us, and that is that the final QC and that is the

final testing that was done to release this particular lot of product into the clinical marketplace was not done using the normal SOP that's associated with this particular product. And also it's not even clear.

I mean, there's a number of crossouts. I'm not sure why that is, but it looks as though it is for the particular lot that this was done for. There is an initial and a date and this is the appropriate way to see something like this.

(Continued next page)

BY MS. HAGBERG:

Q. And could you just scroll down to the bottom?

A. So if you --

Q. Sorry.

A. I just wanted to point out one other thing if you don't mind. And that is that one of the things that we talked about earlier is that every-- any time-- all of the components that we have usually have a lot number associated with an expiration date. And there clearly is no expiration date that could be even on this form. So there's no way to actually record that information easily.

The testing itself is very, very, very unclear. It's not even clear what the acceptance criteria is from this particular form. So, again, the manufacturer of this, the final testing, has to fit -- the output from this should fit within what's called an acceptance criteria. In other words, how does it perform and does it actually perform within these boundaries? You can't tell from this form what that acceptance criteria is. It's completely lacking.

The other problem with this form is that, again, the final QC is probably the most important testing that we do on any product because it really is all of the components together behaving appropriately. This is-- if nothing else, this is the key document in the whole thing.

And this one was reviewed, again, four to five months

after the release of-- five months after the release of the kit. And who performed the test or any of the other information that's required is not on this form.

Q. And did someone sign off on when they dated it 6/25/07?

A. I'm assuming that this person did.

Q. And do you know who-- do you recognize that signature?

A. I do. Livia Calhoun in our company.

Q. And who should have signed off on this form?

A. Quality or somebody in the manufacture-- a supervisor in the manufacturing group. And Livia was not a supervisor at that time.

Q. You can sit down now, Mr. Fryer. I'm going to turn to PTX 211.

MS. HAGBERG: And, your Honor, I'm only going to ask him one question. This is another batch record and I'm not going to make him go through that again.

Q. Have you ever seen PTX 211 before?

A. I have.

Q. And what is this document?

A. Again, this is another-- this is the same product that we were talking about, and that is product reference 822. It's a different lot number which is in the sequence's later lot.

Q. What is the date for this lot?

A. You'll have to turn to the label request page.

THE WITNESS: If I may stand again, your Honor.

THE COURT: Yes, sure.

A. Okay. The lot number for this kit is 0724-- I can't read that. It's-- oh, the box is 072405. That's the kit lot number. And the expiration date of this kit is May 25th, 2008.

Q. And what does column 12 show?

A. Well, first of all --

Q. If you can explain it. Are there other things you have to explain?

A. Yes. Let me explain this whole area. This is the exact same label request form that you had seen previously for the other lot and with all of the various components of the kit with the lot numbers. Now, the unusual part for these lot numbers is that you can see that it has the typical year-year, month-month, day-day. But there's this little letter "A" that follows these. It's not clear what that actually means from this form.

One thing that is somewhat telling, however, is that now the expiration date, which I pointed out previously was one year for each of these various components manufactured by us, is not one year any longer. This one, for example, should have expired on 2007, March 7th. And we can see here that the date is actually longer. It's by three months.

This particular component was, in fact, made long before this. And that is, it was 2006. It should have expired

in 2007, but now we actually have it expiring a year and a half later.

In this batch record, there is no evidence whatsoever that these components were tested in any way, shape or form to be able to justify the extension of this expiry.

So we released this kit with expiration dates which, according to the FDA, is not appropriate without testing.

Q. And have you seen the use of the letter "A" in other batch records?

A. I have. And I've also seen the letter "B" and "C" as well, suggesting that various components-- suggesting that various components were given new expiration dates without necessarily testing it. And I actually know that the practice was pretty widespread at the time.

Q. So you have a personal understanding that that was --

THE COURT: Well, how do you know it was widespread at the time?

THE WITNESS: Because I know that from the director of technical affairs who would assign these new dates.

MR. VELIE: Objection; hearsay.

THE COURT: Sustained. That last answer is stricken.

Q. Could you please take a look at PTX 215? Have you seen this document before?

A. Yes, I have.

Q. And what is PTX 215?

A. This is the-- before the various forms that we looked at are really associated with what's called the standard operating procedure. And this is really the long form that should be followed. So these are the various individual steps that should be followed and the forms themselves, where the information about when that step was performed, the information that was necessary to record.

Q. And when was this SOP in effect?

A. This SOP -- if you could blow up this area here. The effectivity date, or the effective date, of this was April 24, 2006.

THE COURT: Wait a second. Where did you find that? I see it.

THE WITNESS: It's at the very bottom.

THE COURT: Yes.

Q. Would this SOP PTX 215 apply to the lot records that you just reviewed, PTX 210 and 211?

A. It was.

Q. And how do you know that?

A. I know that because the next date of-- typically these SOPs go into revision. And the revision that occurs after this occurs at a much later date beyond the date of manufacture. So the effectivity date of this is the one that's prior to the use of this SOP for the production.

Q. So this is the SOP that should have been followed in

manufacturing of the lots that are shown in PTX 210 and PTX 211. Is that right?

A. That's correct.

Q. And were the procedures shown in PTX 215 followed in the batch records of PTX 210 that you just reviewed?

A. I'm not quite sure. If I could take a quick look back, if that's okay.

Q. Yes. Just please let us know which pages you're looking at so the record is clear.

A. No, this one was not.

Q. And which one are you referring to?

A. So on the previous-- so if you were to look back-- okay. So this is the preparation of-- I'm sorry, if you could scroll to the top.

Q. And when you say "this," you're referring to?

A. I'm referring to the very top of the document itself.

THE COURT: 215.

Q. PTX 215?

A. It's entitled "Preparation of Peroxidase IGG Conjugate." That actually is the detection antibody SOP.

Q. Yes.

A. If we go back to document 91884.

Q. Within PTX 210?

A. Within PTX 210, correct.

Q. Okay.

A. 91884. If you can highlight the top of this. This is the component which was made which I had mentioned was the detection antibody. And this is the SOP which was being followed again, which is, again, the general SOP.

Q. Did other batch records have similar-- similar problems to the ones that you just identified in connection with PTX 210 and PTX 211?

A. Yes.

MR. VELIE: Objection.

Q. And how do you --

THE COURT: She's going to find out through a foundation.

Q. How do you know that?

A. Because I had to do extensive reviews of many of our batch records in 2010.

MR. VELIE: It's the best evidence objection, your Honor.

THE COURT: I'll allow it.

Q. Did the structure of the department that you were in the, the R & D department, change after Sekisui purchased the company?

A. It did.

Q. And at what point in time did it change?

A. In December of 2009.

Q. And how did it change?

A. I was appointed the director of research and development, replacing Robert Greenfield.
Q. And did Mr. Greenfield leave the company?
A. He did not.
Q. Did he leave at some point following that?
A. He did, a year later.
Q. So you took his position as director of R & D. Is that what you said?
A. I did.
Q. And what about Vince Forte? Did Vince Forte leave the company?
A. Vince Forte resigned in January of 2010 and left the company in the end of March of-- or I believe in March-- April of 2010.
Q. And who was hired to take Vince Forte's place?
A. Mr. Kevin Morrissey.
Q. And what changes, if any, occurred after Mr. Morrissey's arrival?
A. Kevin Morrissey looked at our manufacturing group to make improvements in terms of speed and quality and found a number of deficiencies. Not only in the manufacturing group, the manufacturing --
THE COURT: Wait. We had Mr. Morrissey. He told us what he found. I don't need a repeat.
Q. As a result of Mr. Morrissey's findings, did that become

known to everyone in the company?
A. It did.
Q. And what did you do in response?
A. Well, in addition, if I may, there were a number of things that were going on in the company in a very short amount of time. Richard Hart had left our company or went away for a procedure and hadn't been back in a bit of time. We had a recall of one of our products that was ensuing. Our director of regulatory and quality resigned at the end of May.
Q. That's Leigh Ayres?
A. That's Leigh Ayres.
We also had a quality review of our company by an independent contractor who issued a number of reports showing a large number of deficiencies in our quality system.
MR. VELIE: Objection. The reports show what they show and admitted -- if admitted for the limited purposes permitted.
Q. Were you finished with your answer? You can continue.
A. So because of that, there was-- and we also had almost all-- all of our IVD products were put on what's called quality hold. And that is that they could not be released --
THE COURT: Wait. I'm sorry. Mr. Velie was entitled to a ruling. The reports by the quality review company show what they show, not your characterization. So that last paragraph is stricken. But go ahead.

MS. HAGBERG: May he continue?

THE COURT: Do you know where he's up to now?

MS. HAGBERG: I think so.

Q. You were talking about what was going on and what happened.

A. Right. So we had all of our IVD products were on what's called quality hold, and that is that they could not be released until sufficient testing was done to show that the products themselves were testing appropriately. And because of that there was a large amount of work by practically everybody in the company to try to remediate some of these problems. And because of that, there was of course a lot of unease in the employees of the company, just having been acquired by Sekisui and now suddenly almost every one of our business structures were failing in some way, shape or form. They were very concerned.

Q. And so what did you do?

A. I called an employee-wide meeting.

Q. And could you please --

A. I did that by sending out a generalized e-mail to everybody in the company.

Q. Could you please turn to PTX 254?

A. Okay.

THE COURT: One second, please.

A. This is the e-mail that I sent out to all the employees. Shall I read it?

Q. No, I don't think it's necessary.

MS. HAGBERG: Unless your Honor wants him to read it into the record.

Q. What was the point of your e-mail?

A. Was to collect the employees of the company, to very quickly explain to them what we were seeing and to really, rather than listening to everything as innuendo, but to really address them and then to be able to begin the dialogue that was necessary to ease some of their uneasiness.

Q. Would Mr. Hart have been in the active employee list at this time as of May 19, 2010?

A. He would have been, yes.

Q. And did Mr. Hart attend this meeting?

A. No, he did not.

Q. And do you see the top of this document where it says from-- let me withdraw that for a moment.

So the bottom portion of this PTX 254, is that the e-mail that you sent?

A. Yes, it is.

Q. And do you see the top portion where it's from/to? Could you just tell me who that's going from/to?

A. The e-mail is from Richard Hart and it's being sent to himself with a cc to Louise Hart, his wife.

Q. And what is the date of that transmission in relation to the date of the meeting?

A. It's one day later.
Q. And could you read the subject line into the record, please?
A. It says "Company meeting"-- sorry. "Forward: Company meeting regarding issues at ADI need summary from Hugh of meeting."
Q. Did Mr. Hart ever call you to have a summary of the meeting?
A. No.
Q. Did he ever get in touch with you in any other way to have a summary of the meeting?
A. No, he did not.
Q. Was Mr. Hart still coming to the office as of May 2010?
A. No, he did not.
Q. Do you recall having any conversations with Mr. Hart after May 19, 2010?
A. I do not.
Q. And I think you said already that the products were put on hold, but was the R & D group involved in efforts to bring the company into compliance?
A. Very heavily.
Q. And you were still part of the R & D group at this time. Is that right?
A. I was.
Q. What was your title?

A. Director of research and development.
Q. And what was the role that the R & D group and you yourself were playing?
A. The role of the R & D group was fairly wide. We were really at that time -- previous to that time we were involved in really new product development. During this time almost all of our efforts were in either investigating any product problems; number two, trying to release all of our products from quality hold; or, number three, actually developing enhanced SOPs for many of our products.

My own role was numerous, in that I was involved heavily in helping to develop the quality systems at our company including, in fact, the design control system which is what really is the SOP that the R & D group follows.
Q. And were you also involved in a project relating to design history files?
A. I was. Through an investigation that was done, we found that --

MR. VELIE: Objection; hearsay.

THE COURT: I don't know that it is.

MS. HAGBERG: Your Honor --

THE COURT: Go ahead. I don't know what research he's referring to.
A. So the design history files did not exist; they couldn't be found. And I was heavily involved and some of the members of

my group and some of the members from our sister company, SMD, Sekisui Medical, were also involved in recreating the design history files.

Q. And could you please turn to PTX 154?

THE COURT: 164?

MS. HAGBERG: 154.

THE COURT: 154.

A. Yes.

THE COURT: You'll have to pause for a minute. I have to close a bunch of other exhibits. There's too many open, before I can open 154.

Q. What is PTX --

THE COURT: I asked you to wait a second until I can find 154. I'll tell you when I'm ready. Okay?

MS. HAGBERG: Yes.

THE COURT: Okay. Thank you. Go ahead.

A. This is a letter from me -- or an e-mail sent from me on October 18th, 2010, to Joe Azary, who was at that time hired as our director of quality and regulatory affairs. And it was cc'd to both Kevin Morrissey as well as David Teicher.

Q. And what was the point of this e-mail?

A. We were trying to prioritize our efforts in recreating these design history files. And we did so by either risk of the products or by the amount of sales per product. And so I was asked to comment because I knew of the risks and the volume

of sales.

Q. And could you please turn to SEK 664, which is, I think, the third page of PTX 154?

A. Okay.

Q. What is this document showing?

A. These are the-- this is the priority list that we set. And, again, I worked with a number of people in the company to be able to set this. But these are the complete list of exclusively our IVD products. And not just the IVD products that we sell into the U.S., but IVD products that we sell into Europe as well.

Q. And how are you prioritizing them? If you look, the list I believe continues over to SEK 7665. Is that right?

A. Mainly --

Q. I just wanted to make sure you agreed that that was a continuation of the list.

A. This is a continuation of the list. These were, again, our IVD products. And I prioritized them based upon risk, Femtelle being one of the higher risks in terms of its-- in terms of its need in the marketplace as well as the volume of sales that we had for each of these products.

Q. And if you look at the first page of your DHF priorities, it says that a product or device designed prior to 1996 will not be considered. Why was that?

A. 1996 is when the design control document or guideline from

the FDA came out. And from that point forward all products had to conform to the design control system, which means that-- in the design control system by FDA guidelines. All products had to have a design history file. We felt that any product that was-- that was designed and released into the marketplace prior to that wasn't really important because the FDA's priority was to look at the newer records.

Q. And are the products that are identified in SEK 664, are those products that had been on the market prior to October 18, 2010?

A. Yes.

Q. And what about prior to April 2009?

A. Yes.

Q. I don't think I asked you this, but could you please explain what a design history file is?

THE COURT: I think you did ask.

MS. HAGBERG: I did.

THE COURT: Oh, yes.

MS. HAGBERG: Just wanted to be sure.

THE COURT: Right at the beginning of this examination.

Q. Why is a design history file needed?

A. When?

Q. Why is it needed? What is the point?

A. It completes --

MR. VELIE: Your Honor, this was also asked and answered and he gave an expert conclusion to which I objected at the time and I object now.

THE COURT: Yes, I think you also asked why a design history file is needed. I'll sustain the objection.

Q. When does a design history file come into being?

MR. VELIE: This is also asked and answered.

THE COURT: Yes, he did. He said right from the onset, right, the beginning?

THE WITNESS: Yes.

Q. Could you please look at PTX 60 and tell me what that is?

Let me ask you a foundation first: Have you ever --

MR. VELIE: Could you wait a second until we've located the document in the binder?

Q. Okay. Could you please tell me, have you seen PTX 60 before?

A. I have.

Q. And what is it?

A. It's the recreation of a-- or the creation of a design history file for product 860 Imubind tPA ELISA.

Q. When you say "creation," what do you mean by that?

A. Because we did not have compiled design history files, this was actually compiled from various records that we could find either in hard copy or in our electronic system.

Q. And were you involved in compiling or did you oversee the

process of compiling design history files?
A. I was involved in the process.
Q. And how did you go about creating a design history file for a product that was already on the market?
A. First of all, understanding what the product does, we had to collect various records and also the testing that was done in the development phase; looked through laboratory notebooks. Again, the electronic files that we had that had some testing for it.

So anywhere we could find anything that related to the development of, in this case, this particular product, we would-- we started to assemble that. And then by actually parsing the information in the correct way to recreate the history of that, of the development, we were able to put this particular file together.

Q. And were you able to create a design history file-- well, let's just talk about this one-- for 860, product 860, in the way that it would look like if you had started at the beginning of the product as you said it should?
A. No, we couldn't do that.
Q. And why is that?
A. Because typically there is a-- again, going back to 1996 design history-- or the design control system, a guidance that FDA released, there is a very, very well-defined, very controlled process for developing products which really starts

with understanding what the design should be, what is the product, right up until the product is released into the marketplace with very defined steps.

Each of those documents are usually put into a quality system, reviewed, and then signatures need to be-- the signatures are required for that. And then for each stage of development there are also design reviews. Each and every action that is to be taken needs to be approved prior to actually taking that action. And none of those documents actually existed.

Q. Let me ask you to turn to PTX 153. And what is PTX 153?

A. This is a letter-- or an e-mail from me to Martina Kloeppinger, who is the managing director for our German subsidiary, American Diagnostica.

THE COURT: One second. Which is this number?

MS. HAGBERG: PTX 153.

THE COURT: Any objection to this one?

MR. VELIE: No, your Honor.

THE COURT: No?

Q. And what was the purpose of the letter?

A. The purpose of the letter was to explain to Martina why we were having such difficulties in manufacturing various products for her to sell into the European marketplace.

Q. And are you identifying-- what are the products that are identified in paragraph 1 of your e-mail to Ms. Kloeppinger,

PTX 153?

A. The first four products referred to as Femtelle, 812, 813 and 814 are IVD products sold only into the European marketplace as IVDs. The other kits, 810, 825, 815, 815L, 860, 101201, comma, or ellipsis, are products that are sold both in the European marketplace as well as in the U.S. marketplace.

Q. And could you read the part that starts after the first sentence?

THE COURT: "Many of the kits..."?

MS. HAGBERG: Yes.

THE COURT: I'll do that.

"Many of the kits that have been on backorder have been major input from the R & D group. We have suffered many problems with our kits: Anywhere from SOPs that were inadequate or inappropriate, to raw material failures that required R & D effort to help fix."

MS. HAGBERG: That's fine, your Honor.

THE COURT: Okay. Good.

Q. And was that what was going on in the company at the time you sent this e-mail and the procedures that you've just been telling us about?

A. Yes.

Q. Just switching topics a moment, were you involved at all in the efforts to obtain FDA clearance to sell Femtelle in the United States?

A. Not until January of 2010.
Q. And what was your-- what were you doing in January of 2010 with respect to Femtelle?
A. The project leaders, project managers for Femtelle, had requests from FDA for some testing that was necessary for the furtherance of the FDA application, and we were asked to perform those tests.
Q. Could you please turn to PTX 176, please?
MR. VELIE: One second, please. Okay.
Q. Who was working with you on the project that had been assigned to you?
A. Bhavna Gaikwad reported to me in my group in R & D.
Q. Anyone else?
A. Yes, two other members: One was Stephanie Paladini, who was working with Bhavna; and, also, Michael Smirnov, who reported to me. His role was in documenting the necessary validation steps and also as a-- as somebody who would help, I think, in terms of nonwet work, nonbench work. Mostly documentation.
Q. Now would you please look at PTX 176 and tell me what this document is?
A. Oh, I'm sorry, that's the one you have up?
Q. Yes, same document.
A. Okay. This is an e-mail in which I'm trying to describe not only what work was requested of us, but also in our review

of the FDA application-- or the FDA response to our application, what other tests that we deemed were also something that we would probably have to be involved in.

Q. And that was based on your review of what?

A. An FDA reply that was given-- one of the FDA replies to the-- to David Teicher and to Rob Greenfield, who were in charge of the 510(k) filing.

Q. And what was the FDA requiring that was assigned to you to undertake?

A. These--

THE WITNESS: If I may stand, your Honor.

THE COURT: Sure.

A. These four bullet points at the very top are different types of validation assays for some components. One of the things that we were planning to launch within the U.S. is this protein assay. They require what's called a precision study. There are some other supplementary information; however, there's also long-term stability/shelf life study and another study called the Hook Effect. So these were the studies that were requested of us specifically by David Teicher and Rob Greenfield.

There are two additional testings that we thought were very important. And that is-- well, one, really, which is that-- I'm sorry, I didn't read this very carefully.

Actually, what we were asking for on those two second

bullet points really is that we needed to test not only just one lot of material, but that we actually needed a total of three lots of material. So I was requesting that we-- that manufacturing produce two separate lots of kit for us.

Q. And when you say lots of material, what are you referring to?

A. So typically in a kit, we have raw materials as well as the manufacture. What we were looking for specifically -- because the whole purpose of testing three lots is to test all possible variations that could occur in the performance of any kit. So for that purpose, we actually need not only three separate manufacturing of the kits, but all of the various components in that kit should be very different from all other components in any of the other two lots of kit that we were going to be testing.

Q. And you're referring to lots of Femtelle. Is that correct?

A. Correct.

Q. Did you eventually come to have a larger role in the Femtelle 510(k) process?

A. I did.

Q. And what was that role?

A. Right after this period and after-- towards the end of-- well, I should say in May of 2010, there were many questions about the Femtelle filing. We received those both from a consultant who reviewed the application as well as our own

review of the application and realized some great deficiencies in the 510(k) filing.

Q. And was one of the projects that you had to get involved in the review of the batch records for Femtelle?

MR. VELIE: I object to leading.

THE COURT: I'll allow this one.

MR. VELIE: It's too late?

THE COURT: Yes.

A. So our group was also-- our group was also-- we were also involved in some problems that we were having with the product in the April/May time frame. The manufacture-- we found that the manufacture of a particular lot was very different from the manufacture of other lots of Femtelle-- the performance was very different. So we were also involved in trying to enhance the SOPs to assure that the quality of the kit was being tested to the appropriate types of acceptance criteria.

So that was at the end of May. And then we-- so our-- we had been looking at SOPs for Femtelle, but we also needed to look at the SOPs for Femtelle also for-- just to look at the manufacturing practice of that kit for this Femtelle filing.

Q. And did your role with respect to the Femtelle filing increase yet again a little later?

A. It did. I was asked to write a regulatory-- or write an analysis of where we were with the 510(k) filing, which I did in mid to late June of 2010.

Q. And as part of that, did you review the first 510(k) filing that had been made for Femtelle?
A. I did.
Q. And could you please -- this is the other binder. I'm not going to ask you many questions about this, but could you please look at PTX 22?
A. Okay.
Q. Do you recognize this document?
A. This very first document, yes, I do.
Q. And by that I mean the whole document. Have you seen this before?
A. I have.
Q. And what is it?
A. This was the 2007 filing for the 510(k) for Femtelle. 2008, I'm sorry.
Q. And do you know what happened to this filing?
A. It was withdrawn.
Q. Was it withdrawn or did it --
A. It was allowed to lapse.
Q. Were you aware of what issues the FDA had raised with respect to this filing?
A. Towards the end --
MR. VELIE: Objection. I'd like to know what the basis of his knowledge is.
THE COURT: Yes, I agree. So he should give a yes or

no and explain the basis.

A. Yes.

Q. And what is the basis of your answer that you know what the reasons, the objections to the 2007 filing were?

A. Later on, in September, I was looking at what was necessary to actually refile the Femtelle 510(k).

Q. And so you went through the 2007 application as well as the 2009 application?

A. That's correct.

MS. HAGBERG: I didn't know if you were going to rule or if that was okay.

THE COURT: No, it's fine. I'll allow him to testify.

Q. Did you also review the 2009 filings of Femtelle as part of your more central role starting in June 2010?

A. I did.

Q. And could you turn to PTX 23 and see if you recognize this document?

A. I do.

Q. And what is this document?

A. This is a first --

MR. VELIE: Hold it. Please pause for a second. We need to locate the document.

THE COURT: Yes. Which document is this?

MS. HAGBERG: This is PTX 23.

THE COURT: 23? I need to do that, too.

Q. So what is this document, Mr. Fryer?
A. This particular document that we're reading here is an e-mail --
Q. I'm talking about the whole document actually.
A. I'm sorry. The entire document is the 2009 filing of the Femtelle 510(k).
Q. And did you review that Femtelle 510(k) as part of your work on what you said occurred through the summer of 2010?
A. I did.
Q. And what research and clinical test was this 2009 application based on?
A. It was based on data that was collected from the early '90s up through 2006.
Q. As of June 2010, when you got directly involved with the FDA, did you get involved with the FDA in connection with the pending 2009 application?
A. Yes. I was asked to review the filing.
Q. And had ADI received communications from the FDA at about that time period?
A. We had several.
Q. May I point you to PTX 222? And it's in the other binder. You can put that large binder aside now.
A. I have it.
Q. And what is PTX 222? And you might have to start at the back and read forward.

A. So the original e-mail was from Reena Philip, who is the person we communicated with at FDA regarding the Femtelle filing of 2009.

Q. What was her role in the filing process in the FDA side of things?

A. To communicate between FDA and our company.

Q. And who is David Teicher?

A. David Teicher was the director of our technical affairs group.

Q. And why is Ms. Philip communicating with David Teicher?

A. David Teicher was the person who filed the 510(k).

Q. What was the point of FDA's communication with Mr. Teicher as shown in PTX 222?

MR. VELIE: Objection.

Q. Well, let me ask it in a different way.

What were the issues that the FDA was raising in this time period that you were having to deal with?

A. There was-- that our group was directly dealing with was really the validation studies that were missing from the 510(k).

Q. And if you would look at now SEK 720 of Exhibit 222.

A. Yes.

Q. Do you remember Mr. Greenfield making that comment in this e-mail?

A. Yes, I do.

Q. And what was he referring to?
A. We were missing a design history file for Femtelle. It was never compiled at the time of the filing. As part of the design history file are the records that are required for the manufacture of the kits that were to be used in the clinical trials. Those did not exist. We could not find those.
So what he's saying here is that because of this, it was a big compliance problem with the 510(k) file.
Q. And did you raise the missing batch files -- and by "you" I mean ADI -- or did the FDA raise that?
A. We did.
Q. And were you-- did you have a call with the FDA to discuss this issue?
A. We did.
Q. Did you participate in that call?
A. I believe I did, yes.
Q. Do you remember when it was?
A. It was, I believe, in June 2009-- '10.
Q. Who else participated in the call?
A. In my memory, it is David Teicher; Robert Greenfield; I believe Jose Campo called in, our consultant; Kevin Morrissey, Mamoru Koseki.
Q. And what was the purpose of the call?
A. The purpose of the call was to let Reena Philip know that we had some deficiencies in our 510(k) filing and we needed to

ask what steps were necessary to go forward.

Q. And what were those deficiencies? Were those the ones you just explained?

A. The ones I explained in terms of the missing batch records.

Q. And did you have a call with Ms. Philip on June 1 at 2 p.m, as Mr. Greenfield's e-mail indicates?

A. We did.

Q. And what steps did you take after the conversation with FDA? And I'd like to direct your attention to PTX 146. And please wait a moment to answer so that counsel can --

MR. VELIE: Thank you.

Q. Can you please turn to PTX 146?

A. Yes, I have it.

Q. And have you seen this document before?

A. I have.

Q. Did you write this document?

A. I wrote this document.

Q. And could you explain what this document is?

A. This document was written-- was requested by our vice president, Mark Koseki, asking me to outline any of the concerns I had about the 510(k) filing. And this is the nature of the document listing, in broad strokes and specific examples, what the requirements were for the-- what are required by the FDA, what the current status is of our 510(k) filing, and what actions needed to be done to remediate these

problems.

Q. And could you just briefly-- what is the current status column that appears on 485, SEK 485, of Plaintiff's Exhibit 146?

A. It describes the deficiencies with the 510(k) filing.

Q. And what was the first one?

A. We had no design history file for Femtelle. None had been assembled.

Q. And what was the second one on the chart?

A. The second one on the chart was the SOPs for production were very poor, they were inaccurate, and inadequate for the reproducible manufacture of the Femtelle kit.

Q. And what was the third problem that you identified?

A. The quality control documents. That the quality control SOPs did not at that time assure lot-to-lot consistency. And so one thing I had mentioned earlier is that we had noticed that one of the lots of Femtelle that were released into the marketplace significantly differed in performance than the other lots that we had seen because there was no way of controlling that in the older SOPs. We proposed to actually remediate that problem.

Q. In the call that you had with FDA in June, did they respond to your reporting that you had no batch files, batch records, for the Femtelle product?

A. They did. They needed to comply-- they needed to confer

with their compliance officer.

Q. And if you would turn to the next page, SEK 486. And you noted some risks in paragraph 3.

A. Shall I read them?

Q. Yes. Or you can just tell me what the risks were. You don't need to-- if you remember.

A. If you don't mind, I'd prefer to read them.

"Besides a delay in the 510(k) clearance by 9 to 12 months, there's also a risk that a new panel will be filing." In other words, one thing we were worried about is if we were to withdraw the 510(k), the process of having the 510(k) cleared would have been a little more difficult.

But the other consideration at the time, because we had a business that we were trying to run, was the other risks that were to our business. And so one of the fears that we had as a company was that the FDA would come in to do an audit. And if they came in to do the audit, they would discover, first of all, that Femtelle had no design history file, which was against the rules of the FDA, as the FDA requires a design history file to be compiled. Even though it's not submitted, it is a requirement that the companies keep. The FDA would have-- one of the very first things they would want to do is to review that document.

MR. VELIE: Excuse me, your Honor. He's now giving expert testimony. I don't believe it was responsive and,

accordingly, I could not object beforehand. I think it should be struck as opinion.

MS. HAGBERG: I think he was telling what he thought the problems were, your Honor, and why he thought that it would be an issue. He wrote this document and identified the risks.

THE COURT: Risks, right. And he quoted.

MS. HAGBERG: Yes, he read that.

THE COURT: He preferred to read them.

MS. HAGBERG: Correct, your Honor.

THE COURT: Let's see.

THE WITNESS: So --

THE COURT: One second.

MS. HAGBERG: Wait.

THE COURT: I'll allow it to stand. It's his assessment of the risk. Go ahead.

Q. And did you -- after preparing your recommendation, what happened next?

A. We called a meeting of the managing directors at the time to make a decision about what we plan to do with the 510(k) filing.

Q. And could you please turn to PTX 143?

A. Okay.

Q. What is this document, Mr. Fryer?

A. These are the meeting notes from the meeting that I was

describing earlier.
Q. And the attendees, are those the people you recall who attended?
A. I do believe those are the people who attended.
Q. And what was the decision that was made as a result of this meeting?
A. We decided to withdraw the 510(k) filing.
Q. And what was that decision based on? And I'll just help you. If you look at paragraph 3, to save time here.
A. Mark Koseki explained-- it was actually based upon that report that I had discussed earlier.
Q. And did Mr. Hart participate in this meeting?
A. He did not.
Q. And was there any discussion of whether someone had tried to obtain his advice?
A. Yes. We were-- Mark Koseki actually explained that he was unable to have Richard Hart reply to this. And so he used the various documents that we had running our business and found that under these types of circumstances, that the managing board was given the authority to make the decisions, the important business decisions.
Q. And if you look at SEK 612 and SEK 613, did Mr. Koseki attach those e-mails to the minutes when he distributed to the attendees?
A. I believe he did, yes.

Q. Also, I'd just like to ask you about discussion point five that appears on SEK 611 of PTX 143.
A. Okay.
Q. What was-- is DT Mr. Teicher?
A. DT is David Teicher, yes.
Q. And what was Mr. Teicher suggesting?
A. He was suggesting that we actually look for other samples that could potentially be used for another clinical trial.
Q. So what happened after this meeting?
A. We withdrew our 510(k) application. We sent an e-mail -- I believe Dave Teicher sent an e-mail to Reena Philip informing her that we wished to withdraw our application.
Q. Did you continue to review issues relating to Femtelle even after the application was withdrawn?
A. I did.
Q. Could I please direct your attention to PTX 93? What is this document?
A. This document is a regulatory analysis that I prepared to look at some of the-- well, it really is a summary of the history of the 510(k)-- the Femtelle product itself. Everywhere from the beginning of the projects through-- in the original design and who was involved with the designs through the clinical studies which occurred over the course of many years. Also, some of the history that went back and forth between the FDA and ADI following the submission, the May 2009

submission to the FDA.

Going on to then discuss in a little bit more detail than the previous e-mail about the withdrawal of the submission, and then what types of problems there were. Now we're beyond just the submission itself. And then it begins to discuss what actions are needed prior to the resubmission to the FDA.

Q. And what page are you referring to when you say what actions are required for --

A. That is on page SEK 1030432.

Q. And just before we get to that, could you please tell me when you prepared this report?

A. Yes. The completion of the preparation of this report was August 29th, 2011.

THE COURT: I'm sorry, is that Exhibit 93?

MS. HAGBERG: Yes, your Honor, this is PTX 93.

Q. And in the introduction that appears on 422, could you just read into the record the last sentence of that introduction?

A. 4.2.2?

Q. 422. Page SEK 422 of PTX 93.

A. I'm sorry.

Q. It's up on the screen here.

THE COURT: The last line of the introduction?

MS. HAGBERG: Yes.

THE COURT: "Based upon the actions outlined in this

document and RA/QA analysis, an action plan and time line will assembled to resolve these issues so that a plan for 510(k) submissions can be made."

Q. Okay. Can you now turn back to SEK 432, which you said was the actions that you had identified needed to be taken before resubmission to the FDA? Do you see that?

A. Sure.

Q. And what-- sorry. Go ahead.

A. So these are the various actions which have to do with the clinical trials that were performed previously. And we needed to get some information from our clinical partners that performed these studies, which include the information that was requested by the FDA.

Based upon what we found there and what was lacking, we need to then determine if we needed to rework some of the clinical data to include only those patients that we had sufficient information for. We needed to reassemble-- to assemble a retrospective design history file, update the design history file with any new potential design changes and data pertaining to any of the verification studies that we would have to do after the new design was put in place.

And then, also, we didn't at the time of the filing have control samples that, generally speaking, all of the clinical laboratories, at least in the U.S. and also in Europe, really require to determine if the kit is working

appropriately, at least in their hands. And we needed to find a way of seeing if we could obtain one of those.

Q. And did you try to track down the data from the earlier studies that I think you said occurred in 1999?

A. I did.

Q. What did you do?

A. I contacted first one of our clinical partners, Manfred Schmitt from Technical university of Munich, to see if he could track down some of this information that the FDA was asking of us.

Q. And when was that that you undertook that?

A. I'm not exactly sure.

Q. Was it after the date of this report?

A. I believe so, yes.

Q. And how long did you continue to work on the issues that are identified here?

A. Till 2011.

Q. And you say in 6.6 on SEK 433 that "a possibility was submission of a Femtelle pre-IDE to FDA."

What did you mean by that?

A. Pre-IDE is basically an outline of what your plans are for the development-- or for the submission of a product to the FDA. It's more or less kind of a compressed version, an incomplete compressed version of what the filing would look like.

Q. And in light of the activities that you identified in Section 6 of this document, did ADI make any conclusions on what to do next and after the work you said you undertook?
A. We continued to investigate whether we can move forward with this project and try to determine ways in which we could complete any studies that would be necessary for the 510(k) submission.
Q. And did ADI reach a conclusion on whether you would be able to file another 510(k) any time soon?
A. We did, and it looked like we probably would need to do further clinical studies.

MS. HAGBERG: I have no further questions.

MR. VELIE: Your Honor, before cross, may we have a comfort break?

MS. HAGBERG: Your Honor, may I just read into the record my exhibits?

THE COURT: If you need a break, take a break. You can start now. You don't need to stay for the reading of the exhibits. Go ahead. Go ahead.

MS. HAGBERG: Your Honor, may I?

THE COURT: Yes, please.

MS. HAGBERG: PTX 210, PTX 211, PTX 215, PTX 254, PTX 154, PTX 60, PTX 153, PTX 176, PTX 22, PTX 23, PTX 222, PTX 146, PTX 143, and PTX 93.

THE COURT: Okay. Thank you. As soon as Mr. Velie

returns, we'll start the cross.

They're all received.

(Plaintiff's Exhibits PTX 210, PTX 211, PTX 215, PTX 254, PTX 154, PTX 60, PTX 153, PTX 176, PTX 22, PTX 23, PTX 222, PTX 146, PTX 143, and PTX 93 received)

THE COURT: All right. Whenever you're ready, Mr. Velie.

MR. VELIE: Your Honor, I won't be ready until I have Ms. Briley back to hand me exhibits. I'm sorry.

(Pause)

CROSS-EXAMINATION

BY MR. VELIE:

Q. Mr. Fryer, I believe you testified that you were a participant in a call with the FDA on or about June 1. Is that correct?

A. I was.

Q. And you gave some testimony about that call?

A. I did.

Q. You're aware, are you not, that there are actually minutes of that call?

A. There are.

Q. You saw them?

A. I did.

MS. BRILEY: Give me one moment, your Honor. Thank you.

Q. Do you recall that Ms. Philip, the representative of the FDA, told you in the call that what she-- her response mainly focused on "urging us to submit whatever data we had as soon as possible"?

MR. VELIE: And that's at the very bottom of the page, your Honor.

Q. Do you recall that?

A. I do.

Q. And then you go on to the next page, and she asks you about what you achieved so far in response to the letters.

Do you recall that specifically-- I'm reading from paragraph number 3 -- she asked about the three-lot precision study.

A. I'm sorry, I'm not sure which --

THE COURT: Third line on the second page which ends with 5781, the numbers 5781 in the lower right-hand corner.

Do you see the lower right-hand corner of the page?

THE WITNESS: Yes, I do.

THE COURT: 5781. So paragraph 3 at the top, the third line says "Specifically, she asked about the three-lot precision study."

THE WITNESS: Yes.

THE COURT: You responded that "Two lots were made and tested and we were having trouble manufacturing the third lot because of the raw materials supply problem. Reena said to

send in the data on the two lots."

(Continued on next page)

Q. Is that correct?
A. Yes.
Q. That's what she said, send what you've got?
A. Yes.
Q. All right. Number three, you have a protein assay that's been completed. She said send it in, right?
A. Correct.
Q. Okay. I'm not going to read everything in paragraph C, but the status of a clinical study was raised by the FDA.
THE COURT: And it ends with again they urge us to get the data in to them as soon as possible so they could review it.
Q. Is that right?
A. Yes.
Q. She wanted this material so she could review it?
A. She did.
Q. The next paragraph talks about something that's being done by your statistician, I believe, and you say, "We will be able to have Ron Cates provide the numbers in one table and the provisional factors." That's what she was asking for, the one table?
A. Could I just clarify? That was actually Rob Greenfield, not me.
Q. But you were on the call?
A. I was.

Q. And the "we" is the company?
A. Correct.
Q. Okay. And the next one, there's an issue about 95 percent CI for the ten-year chemo NO study. Do you see that?
A. Yes. I do.
Q. She said, if you could get these data Reena seemed to indicate we could claim ten years on the prognosis. If we don't get the data we'll be restricted to a five-year cycle. Is that what she said?
A. Yes.
Q. Yes? Okay. Again, urging you to send in materials?
A. Correct.
Q. And followup discussion after the phone call. You couldn't tell if the lack of batch records was a complete no-go on submission, is that correct?
A. Correct.
Q. She never told you that that's a problem.
A. Correct.
Q. In fact, you had volunteered the issue that you didn't have batch records and kept asking her is this a problem, is there a problem and they never told you it's a problem. That's correct, isn't it?
A. Correct. Can I clarify?
Q. You may do that on Ms. Hagberg's time.
On the other hand, I'm reading from the second half of

that A paragraph. "They were pushing hard for us to provide them with whatever data we had or will have in hand before the deadline. They even wanted, in fact strongly encouraged, to provide incomplete studies, i.e., lot-to-lot precision."

But then you note in the next paragraph there was also a strong concern expressed that if we complete the filing this will initiate an early audit by FDA. You're now not talking about what Ms. Phillip said, you are talking about your meeting with the people who were on the phone with you, isn't that correct, from the company?

A. Yes.

Q. After this, quote, "There was no clear recommendation for which strategy to take." Is that correct?

A. Correct.

MR. VELIE: Your Honor, we have an exhibit that's similar to one of the plaintiff's exhibits but I'm going to use mine because they left off some of the information. This is our Exhibit GG and it corresponds to Plaintiff's Exhibit 29, only it has -- I'm sorry, 222.

MS. NOLEN: Which is a part of this e-mail.

MR. VELIE: Okay. So this is the complete e-mail chain.

Q. I'm going to read now to you or ask you if you recall seeing a response from the FDA on June 28, 2010.

A. I'm sorry, did you ask a question?

Q. Not yet.

THE COURT: Well, he sort of did. He said do you recall receiving this e-mail or reviewing it, one dated at the top June 28, 2010 from the FDA Ms. Phillip.

Q. Have you ever seen it?

A. I've seen it, yes.

MS. HAGBERG: Your Honor, I'm not sure what --

MS. BRILEY: I gave you the wrong --

MS. HAGBERG: I have a wrong document.

MR. VELIE: He was given the wrong document. I'm sorry.

MS. BRILEY: That was marked incorrectly. That's your plaintiff's document. Let me hand you DX GG, which is the same document. It just has a different number.

THE COURT: I have it as PTX 29, which is the same. Whether it's GG or 29 it's the same document. The question is --

MR. VELIE: It's not the same, your Honor. There's an important difference.

MS. BRILEY: Right. PTX 29 and DX GG are the same document, but PTX 222, which they introduced, is similar to DX GG but not the same. So we are introducing DX GG but you have a marked copy.

THE COURT: The question is, the June 28, 2010 e-mail from Ms. Phillip to David Teicher, do you recall seeing it?

MR. VELIE: And the answer was yes.

A. Yes.

Q. Is that correct? And what Ms. Phillip said, she's talking about the lost batch records due to your site change. Meaning you, the company, had explained to the FDA that you simply lost some old batch records, correct?

A. Could you point to the document that you're referring to? Is it the 222?

Q. GG. Look for one that has a GG stamp on it.

MS. BRILEY: It's the one I just handed to you, Mr. Fryer, it says PTX 29.

THE COURT: She just handed it to you. PTX 29, it's the same document.

A. Okay.

THE COURT: And the question is --

THE WITNESS: I'm sorry I have DX LL, I don't have a GG.

THE COURT: Do you have PTX 29, 0029 that was just handed to you?

THE WITNESS: No.

THE COURT: I bet you do. I bet you have it right in your left hand but don't know it. Okay.

THE WITNESS: Oh, I'm sorry. I'm sorry, your Honor.

THE COURT: That's okay.

THE WITNESS: Okay.

Q. Do you note that Ms. Phillip of the FDA said even if you lost the batch records due to your site change the principal investigator of your clinical validation study should have the information regarding the lot numbers they purchased from you to conduct those studies. You could collect that information from them for your records. Is that what the FDA told you?
A. That's in the e-mail, yes.
Q. They didn't need to have them submitted to the FDA. They wanted to you collect them if you could, put them in your records, is that correct?
A. That's correct.
Q. Okay. In fact, the issue is as the meeting minutes show, the people present at that meeting, did that include Mr. Morrissey?
A. It did.
Q. It included Mr. Campo?
A. He called in.
Q. The people present at that meeting feared that there would be an audit that you would not pass, is that correct?
A. That's correct.
Q. Okay. And it is the fact that you were in fact audited by the FDA a little bit after this and passed, isn't that correct?
A. The year after, yes.
Q. I want to take a look now at PTX 93. I used this a few moments ago.

A. I have it.
Q. You have it in front of you?
A. I do.
Q. Basically, what you're doing here is you're reviewing what the issues might be and you are, are you not, sir, recommending that they go forward with the Femtelle project?
A. I recommended not going forward with the Femtelle project.
Q. Look at the back page.
A. Oh, I'm sorry. I misunderstood your question. I thought you meant were we recommending to withdraw our 510(k). I did recommend that. I did recommend moving forward with the Femtelle project, yes.
THE COURT: You said look at the back page. What's the last four digits?
MR. VELIE: 433.
THE COURT: I'm in the wrong place entirely. I don't have 433.
Q. Let's be clear. There's a little confusion of time between us. You've testified and I'm aware that you recommended withdrawing the then-pending Femtelle 510(k) in or about June, I think it was 29th of 2010?
A. Yes, I did.
Q. And this document which I'm now working with you on, PX 93, was offered subsequent to that, isn't that correct, after 2009 was withdrawn?

A. Yes, it looks like a year later.
Q. And so you're reviewing what was going on with Femtelle and your basic recommendation is let's go forward with Femtelle, isn't that right?
A. Correct.
THE COURT: Where will I see that?
MR. VELIE: At page 0429. In the middle of the document.
THE COURT: Ah.
MS. BRILEY: Your Honor, this was page 033 where he was -- are you asking him which page you would find that on?
THE COURT: He said 429?
MR. VELIE: 33 is the page he gives his recommendation.
THE COURT: 33. Let's try that. Where do you see that on 33?
MR. VELIE: Because of the various outstanding issues a pre-ID is recommended for Femtelle.
THE COURT: I see.
Q. But basically you're saying let's go forward, we need to do a pre-ID first?
A. That's correct.
THE COURT: What's a pre-ID?
THE WITNESS: That's essentially a plan you review with the FDA to let them know what you'd like to do with the

510(k).

Q. Now let's turn to page 429 of this document. By the way, you wrote this document, is that correct?

A. I did.

Q. And you wrote it to your management so they could make an accurate assessment of what to do?

A. I did. I actually wrote it for quality systems so we had this document so we could review it at any time.

Q. And look in paragraph 4.4 on page 429?

A. Yes.

Q. The lead of which is FDA questions to the ADI response and you point out May of 2010. Is that correct?

A. Yes.

Q. Those responses were at the FDA and were the subject of the telephone call in June that we just talked about, isn't that correct?

A. It is.

Q. And now I want you to read out loud what paragraph 4.42 says.

A. Quoting again, reading from the document. "Many minor points were raised in these comments, all of which could have been answered by ADI. However, no actions were taken as the submission was withdrawn.

Q. I see. You happen to know, do you not, sir, that Mr. Teicher, who was in charge of dealing with the FDA on this

project, recommended going ahead with the filing in '09?

MS. HAGBERG: Objection.

Q. Actually '09 and '10.

THE COURT: If he knows it, he knows it. Do you know any such thing?

THE WITNESS: He did.

Q. He did?

A. He did.

Q. You know because you communicated with Mr. Morrissey that he actually believed it would be approved in the summer, isn't that correct?

THE COURT: He? Who is he?

MR. VELIE: He, Morrissey.

THE COURT: Did you know that Morrissey believed it would be approved in the summer?

A. No, I don't believe he did but I don't know.

Q. I have something to refresh your recollection.

A. Sure.

MS. HAGBERG: Your Honor, they could have asked Mr. Morrissey about this a half an hour ago.

THE COURT: Yeah, we could have. This is just to refresh recollection, though, right, or wrong?

MR. VELIE: I think we can do that. Your Honor, would you like to use the plaintiff's designation? They put it on their list. We never objected to it or we have a designation

of our own.

THE COURT: Doesn't matter.

MR. VELIE: Let's go with the plaintiff's designation.

THE COURT: Which is?

MR. VELIE: 152.

THE COURT: But you're just using it to refresh recollection anyway. So he's going to show you an e-mail that you sent on April 20, 2010 and read it to yourself and see if it refreshes your recollection.

THE WITNESS: It does.

THE COURT: Oh, good.

Q. In fact, didn't Morrissey tell you in April that he thought it would be cleared by the summer?

A. I don't recall that he did, no.

Q. But you wrote that to him, didn't you?

A. Actually, I, what I believe I wrote was that we were looking at what possibilities there were, and I believe that one possibility is it would be cleared and the other possibility it wouldn't be cleared. We were looking at scenarios.

Q. I just want to read to you what you said when you wrote to Mr. Morrissey, Dicey Taylor -- I think that's it. "This is especially true, as you pointed out yesterday, given that we will likely have Femtelle cleared by the FDA by the end of summer." Is that what you wrote?

A. Can you point to me which page you're --
Q. On the very first page of the exhibit.
THE COURT: I don't know where you are either. Are you in the June 28 -- no.
MR. VELIE: April 20, 2010.
THE COURT: There it is, right. "This is especially true." Third line, top e-mail.
THE WITNESS: I see it, yes.
THE COURT: "This is especially true as you pointed out yesterday, given that we will likely have Femtelle cleared by the FDA by the end of the summer and will be submitting at least three more filings within the next month." You wrote that?
THE WITNESS: I did write that, so -- I wrote that.
Q. And you wrote it because you then recalled, did you not, that Mr. Morrissey had said exactly that? Yes?
A. I guess I'm a little confused because I remember having many discussions with Mr. Morrissey about the FDA filing in April -- in this particular time frame we discussed a number of different scenarios and I don't believe that Mr. Morrissey actually really understood what the filing looked like and I think that was one of the reasons why he wanted Jose Campo to review it.
Q. The fact is in 2010, at the time that you were discussing whether or not to withdraw this filing, a big concern came up

because of audit, is that correct, the fear of an audit?
A. Correct.
Q. And at that time, as you testified, you were not an expert in compliance, is that correct, sir?
A. That's correct.
Q. But Mr. Morrissey told you he was an expert, didn't he?
A. He said that he had great knowledge in that area, yes.
Q. And Mr. Campo was a person who you thought had great knowledge in that area, is that right?
A. I do believe so, yes.
Q. And both of them were recommending let's do all of this changing everything around because we might get audited, is that correct?
A. Correct.
Q. In fact, you told us that you called a big meeting in May of 2010?
A. I did.
Q. Only two and a half weeks after that there was an Intertek audit which you passed, isn't that correct?
A. That's correct.
Q. Did you ever come to the conclusion that Mr. Campo was extreme and therefore didn't really know what he was talking about?
A. I came to the conclusion that Mr. Campo was extreme. Whether he knew what he was talking about, I do believe I think

he knew what he was talking about.

THE COURT: What do you mean by extreme, then?

THE WITNESS: He believed that we needed to do -- that the level of compliance that we needed immediately was very, very high and I think that that does not necessarily make good business sense because that would have shut us down.

Q. So you changed your mind? I mean, as you got more expert in FDA compliance you came to the conclusion that Mr. Campo was extreme, is that correct?

A. No. I came to the conclusion because I found that every time it seemed like he was continuing to accelerate some of the things that he was seeing.

Q. I'm sorry, I didn't understand that.

A. Every conversation we had with Jose Campo seemed to be every time he would come back to us there were more and more items that he wanted to add to his list.

Q. Okay. I'm going to show you what we've marked Defendant's Exhibit ZZZZZ.

MS. BRILEY: I'd like to explain to the Court that we have included the metadata for this exhibit because it's an Excel file and doesn't have a Bates stamp.

THE COURT: Okay. Five Z's.

Q. Do you see this document?

A. I do.

Q. You prepared it, didn't you? Do you want to look at the

metadata? It tells us you did.

THE COURT: It says author Hugh Fryer.

Q. Do you remember preparing this?

THE COURT: What's your question? I'm sorry?

Q. Do you remember preparing this?

A. Yes, I do.

Q. Okay. And the first risk reduction category you talk about in box number 1, the upper left, is panic in our lawyers. At the time you prepared this, which was in 2011, actually, I'm sorry. It's created on March 24, 2011 at 7:06 p.m. and last modified three days later. Is that correct, sir?

A. Yes.

Q. You wrote down that there was a risk here because of, quote, "panic in our lawyers."

A. Yes.

Q. Had that panic been created by Mr. Morrissey and Mr. Campo?

A. At the time I believed, yes.

Q. Okay, and at the time you had come to the conclusion, hadn't you, that panic is not a good thing and that they had been too extreme and caused this reaction in the lawyers, isn't that correct, sir?

A. That's correct.

Q. And the next thing you say is, "Risk cause, Jose's extreme view of ADI's quality system," is that correct?

A. Yes. That's what it says here, yes.

Q. And then the action you plan is show lawyers that our risks are not as extreme as portrayed by Jose. Write letter of explanation of the extreme viewpoint of Jose and the financial conflict of interest. Is that correct? You wrote that?
A. I did. I did write this.
Q. What financial conflict of interest were you talking about?
A. He was asking for quite a bit of money for his services.
Q. And you had concluded that this had clouded his judgment, is that correct, sir?
A. That's correct.
Q. "Detail: Call a tough independent auditor that has no financial stake in being tough." That was your recommendation?
A. It was.
Q. Did you ever make these recommendations to the company management?
A. I don't recall who this document went to. It might have been just from my own notes.

MR. VELIE: Your Honor, we're going on to something that will take a great deal of development. I'm only wasting three minutes of our time. May I please stop here?

THE COURT: No. And it's not three, it's six. According to the computer, it's 4:24.

MR. VELIE: Okay, I'll go on to something that I think will be a little quicker.

THE COURT: Okay.

MR. VELIE: Defendant's Exhibit EE.

MS. BRILEY: One moment, your Honor, please, while we pull up the document. We only have one copy for the Court.

THE COURT: That's okay. Thank you. All right.

Q. In or about June 30, 2011 were you the officer at the company in charge of the Femtelle product?

A. I was.

Q. Were you consulted by the company in connection with what it was going to tell the auditors with respect to the Femtelle assay?

MS. HAGBERG: Your Honor, I'm going to object to the use of this exhibit with this witness because this is related to Sekisui America Corp. which has nothing to do with Mr. Fryer.

THE COURT: Well, I don't know that. Maybe if he interacted with KPMG or provided them with information that's something he can be questioned about but I don't know if he did. We'll see. What was your question again, Mr. Velie?

Q. Did they consult you?

THE COURT: Who they?

MR. VELIE: The company management.

THE COURT: Sekisui.

MR. VELIE: Anybody in the Sekisui family.

THE COURT: Okay.

Q. Consult you with respect to your views as to the possible

success of the Femtelle project?
A. I believe so. Without looking at this document carefully I would have to agree with you.
Q. And on page 4 of the document, which is Bates stamped 941 -- this document, by the way, do you recognize it as a report by KPMG?
MS. HAGBERG: Objection, your Honor. He hasn't set a foundation --
MR. VELIE: I'm asking.
THE COURT: I was going to say we'll find out.
A. I'm assuming so because it says so at the top.
Q. Do you remember that KPMG were the financial auditors for the Sekisui group?
A. I do remember that.
Q. Okay. And I'm going to read to you what it says on page 4 and ask you if this is consistent with the information you gave to the management in order that they could talk to KPMG. "For the Femtelle project, please indicate the probability of success for completing the project: A, quality system improvement. ADI has already improved many issues. The realtime stability data collection will be completed in 2012 as scheduled, probability 100 percent. Clinical data of Femtelle. ADI has already started with the outside partner to review the data ADI collected in the past. To identify each data with the patient information as required there is a limitation to manage

the time line of the project, probability 70 percent. Total probability 80 percent."

So that's the overall probability of success for completing the project, is that correct?

A. It says so here, yes.

Q. Is that consistent with the information you gave to your management so that they could talk to the auditors?

A. I really wish I could say. I don't recall.

Q. You don't recall.

A. No.

Q. Okay.

MR. VELIE: I do believe I've reached the end of the day and I'm ready to offer this document as self authenticating. It's been produced to us and not objected to.

THE COURT: A different document?

MS. HAGBERG: Same document.

THE COURT: Okay, you'll do it at the end. If it's been produced to you and no objection, that's it.

MR. VELIE: May I break for the day?

THE COURT: After she's done with the list of exhibits.

MR. VELIE: I'm not done with the witness.

THE COURT: I realize that. You'll come back at 10:00.

MS. BRILEY: Exhibits DX GG, we produced that as PTX

152, DX five Z's, DX two E's.

THE COURT: I don't think you did introduce it as 152. It was 29.

MS. BRILEY: Did we introduce 5 W's as 5 W's?

MS. HAGBERG: I think 152 was just to refresh his recollection.

MS. BRILEY: Are we introducing that --

MR. VELIE: We're moving it into evidence.

THE COURT: Which one?

MS. BRILEY: PTX 152.

THE COURT: Okay. The 2 G's was 29.

MR. VELIE: May we have an order that the witness --

THE COURT: Yes. You're on cross-examination now. Once you're on cross-examination you can't speak with plaintiff's counsel. You understand. I mean, you could speak but about the weather and about the rain and sports, but not about the case. That's it.

MR. VELIE: There are also experts and others on the team. He's not to speak with them either.

THE COURT: It's all true. Whatever else is interesting to you, but not the case, which isn't all that interesting. Okay. Thank you.

See you all tomorrow at 10:00.

(Adjourned to January 15, 2014 at 10:00 a.m.)

INDEX OF EXAMINATION


| Examination of: | Page |
|---|---|
| KEVIN MORRISSEY | |
| Direct By Mr. Whitney . . . . . | 154 |
| Cross By Mr. Velie . . . . . | 212 |
| Redirect By Mr. Whitney . . . . . | 255 |
| Recross By Mr. Velie . . . . . | 257 |
| HUGH FRYER | |
| Direct By Ms. Hagberg . . . . . | 261 |
| Cross By Mr. Velie . . . . . | 335 |


PLAINTIFF EXHIBITS


| Exhibit No. | Received |
|---|---|
| 225 . . . . . | 166 |
| 228, 225, 172, 231, 46, 53, 213, 84, 101, 235, 99, 165 and 17 . . . . | 212 |
| PTX 210, PTX 211, PTX 215, PTX 254, PTX 154, PTX 60, PTX 153, PTX 176, PTX 22, PTX 23, PTX 222, PTX 146, PTX 143, and PTX 93 . . . | 335 |


DEFENDANT EXHIBITS


| Exhibit No. | Received |
|---|---|
| LLLLL, KKKKK, IIIII, V, and E . . . . . | 260 |